Procedure for Biomedical Equipment Calibration and Maintenance

1.0 Purpose– This procedure specifies the schedule and requirements for calibration, performance verification, and maintenance of Biomedical equipments.

2.0 Scope– This procedure applies to the critical laboratory equipment used by the Blood Banks in Govt Hospitals of Punjab state.

3.0 Definitions

- **Calibration** – Adjustment or standardization of the Accuracy, Linearity and Repeatability of a measuring instrument, usually by comparison with a certified reference or standard.
- **Certified Reference Material (CRM)** – A reference material whose property values are certified by a technically valid procedure and accompanied by or traceable to a certificate or documentation issued by a certifying organization.
- **Critical Laboratory Equipment** – Analytical instrumentation and equipment affecting the accuracy or precision of a test method.
- **Performance Verification** – The confirmation of the reliability of a previously validated method(s) or equipment.
- **Quality Assurance Checks** – Periodic confirmation of the reliability of equipment, instrumentation, and/or reagents.
- **Reference Standard** – Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
- **Traceability** – The linking of measurement standards and/or measuring instruments to relevant national or international standards.

4.0 Procedure

4.1 General Equipment Requirements

4.1.1 The User shall maintain an equipment inventory that shall include the following information:

- Equipment name, including software and version.
- Manufacturer and model.
- Serial number or other unique identification.
- Location.

4.1.2 All equipment in the equipment inventory system shall be identified uniquely (e.g., DOJ bar code number).

4.1.3 All equipment shall be maintained in good operating order and according to manufacturer and/or Section maintenance requirements.

4.1.4 All critical equipment shall be calibrated once in a year or verified before major repair / maintenance.

4.2 Equipment Calibration and Verification

4.2.1 User shall include procedures for calibration and/or performance verification of new equipment in Section technical procedures.
Page 1/4
4.2.2 Calibration procedures shall be appropriate for the intended use of the equipment and shall provide criteria for determining if calibration is satisfactory.

4.2.3 Reference Standards

4.2.3.1 Whenever possible, reference standards traceable to SI units (International System of Units) shall be used. In situations where SI units cannot be used, certified reference material provided by a competent supplier shall be used if available.

4.2.3.2 Reference standards shall be calibrated by an accredited organization or vendor that can provide proof of traceability. These typically would include, but not be limited to, ISO 17025-certified companies.

4.2.3.3 Reference standards shall only be handled by employees authorized by the User and shall be stored to prevent contamination and/or deterioration. Reference standards shall be calibrated before and after any adjustment. All reference standards, certified reference materials, or reference materials used for calibration shall be uniquely identified.

4.2.4 Manufacturer operating manuals shall be consulted to determine the correct calibration interval. Equipment which requires calibration shall not be used if satisfactory calibration cannot be achieved or the calibration date has passed. Equipment used infrequently, such that the manufacturers' recommendations cannot be followed, shall have calibration verified prior to use. Prior to being used in testing, new equipment (or any piece of equipment which leaves the control of the Laboratory e g shifting) shall undergo calibration procedures or performance verification.

4.2.5 Calibration records shall be maintained and associated with the unique identifier of each piece of equipment. These records shall include:

- Identity of the biomedical equipment and software.
- Name of manufacturer.
- Serial number or unique identifier.
- Date of calibration.
- Current location.
- Manufacturer's instructions or a reference to location.
- Reference standard, certified reference material or reference material used for calibration.
- Copies of all reports, results of calibration, and/or certificates of calibration.
- Maintenance plan and due date for the next calibration.
- Identity of the individual performing calibration.

4.2.6 When external calibrations are performed, service providers that demonstrate competence, measurement capability,and traceability shall be used. Calibration certificates from these providers shall

contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification. When possible, providersaccredited to ISO 17025 shall be used.

4.2.7 If calibrations are performed by an outside vendor, the user shall maintain the original calibration records provided by the vendor and a copy of the relevant records shall be readily available.

4.2.8 Biomedical equipment requiring calibration shall be labeled or coded to indicate the calibration status, including the date when last calibrated and the due date for recalibration (or expiration criteria for when recalibration is due).

4.3 Equipment Maintenance

4.3.1 Equipment shall be maintained as specified in the technical procedure.

4.3.2 Critical equipment shall have documented procedures for the maintenance process. Maintenance procedures and frequencies, either in the form of vendors' manuals or in-house procedures, shall be available for each piece of equipment. The operating and maintenance manuals shall be readily available to the operator. In the absence of manufacturer's instructions, instructions shall be provided in the technical procedure.

4.3.3 Preventative maintenance procedures (other than basic cleaning) for each equipment item shall be developed by each Section unless already described elsewhere (e.g., the equipment manual) and shall be performed according to a regular, predetermined schedulei.e**twice in a year**. Preventive maintenance shall be documented in the maintenance records.

4.3.4 After receiving complaint from the user via email/phone ,the service engineer visit the site within 48 hours. In case spare is required complaint should be closed within seven working days.

4.3.5 Certain critical equipments like Auto Haematology analyser, Fully Auto Biochemistry analyser, Dialysis machines, CR systems,Phaco Emulsification machines, yag Lasers and CT Scan are serviced by the original equipment manufacturer. Contract of CAMC is reviewed on yearly basis.

4.4 Maintenance Records

4.4.1 Maintenance records shall be maintained and shall include:

- Type of equipment.
- Equipment serial number or unique identifier.
- Date of maintenance.
- Adjustments or repairs made.
- Identity of the individual performing maintenance.

4.4.2 If maintenance is performed by an outside vendor on a lab-wide basis (e.g., microscope maintenance), the user shall retain the original maintenance records provided by the vendor.

4.4.3 When a piece of equipment is retired from service, maintenance and repair records shall be incorporated into the Section archives by the User.

4.5 Out of Service Equipment

4.5.1 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated and/or clearly labeled (Out of Service – Do Not Use) to prevent use until repaired and shown by calibration or test to perform correctly.

4.5.2 Prior to returning a piece of equipment to use (out of service for any reason - e.g., maintenance, malfunction, leaving the direct control of the Laboratory), correct operation shall be demonstrated by calibration or performance verification. Laboratory personnel shall examine the effect(s), if any, of a malfunction on analysis results and implement the Procedure for Corrective Action as required.

4.5.3 An exception may be made if the equipment failure is not directly related to its analytical function, such as a problem with peripheral equipment.

4.6 Quality Assurance Checks - Quality assurance checks may be carried out at appropriate intervals to verify that equipment is functioning as expected. The procedures for quality control/assurance checks shall be included in the technical procedure for which the equipment is being used.

4.7 Correction Factors- Where calibrations give rise to a set of correction factors, the Section shall ensure that software is updated with these correction factors.

4.8 Safeguards- User shall designate the personnel (to Monitor Equipment) responsible for equipment calibration, maintenance (including outside vendors used for these services).

5.0 Records

- Listing of critical equipment requiring calibration and/or maintenance
- List of authorized equipment service providers (as per recommendation of Original Equipment Manufacturer)
- Calibration, maintenance and verification records
- Service and repair records
- Certificates of traceability for reference standards

6.0 Attachments N/A

7.0 Revision History

Effective Date	Version Number	Reason	No of pages
26/01/2017	1	Original Document	4

Prepared By

Name:

Signature

Reviewed By

Name:

Signature

Approved By

Name:

Signature