**Model SOP**

**Standard Operating Procedure**

**Name of the facility / activity : Equipment Maintenance – Preventive Maintenance**

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| **SOP no.**  | **Effective Date** | **Pages** | **Prepared by**  | **Authorised by**  |
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| **LOCATION** : Quality Assurance Laboratory / Red Cell Serology Laboratory |
| **SUBJECT** : Equipment Maintenance  |
| **FUNCTION** : Preventive Maintenance |
| **DISTRIBUTION**: Quality Assurance Manager / Medical Officer / Supervisor Blood bank Master File |

1. **SCOPE & APPLICATION:**

This procedure covers those measures taken to ensure the integrity, accuracy and reliability of measurement data for equipment and instruments used in the collection, testing and storage of blood products. The procedure is applicable to all equipment used to control or evaluate suitability of starting materials, in process products and finished products.

1. **RESPONSIBILITY:**

It is the responsibility of the supervisor of the section to which the equipment belongs to:

1. Plan, schedule, organise and maintain records of the calibration programmes for various equipment under their control.
2. Ensure that equipment and instruments are continuously calibrated or are removed from use.
3. The Supervisor should train staff for performing calibration/performance checks.
4. **DEFINITIONS:**

 ***Calibration:***

A set of operations which establish under special conditions the relationship between values indicated by measuring instruments and standards.

***Performance checks:***

The routine checking of the performance of an instrument to verify that it has remained within specified range of accuracy and precision.

***Accuracy:***

The closeness of agreement between the result of a measure and the true value of measurement. Calibration is used to determine the accuracy of an instrument.

### Precision

*(Repeatability*)

The closeness of agreement between the results of successive measurement of a defined procedure several times under prescribed conditions.

***Measurement standard:***

A measuring instrument or material which physically defines a unit of measurement or value of a quantity. Measurement standards used for calibration should be traceable to the SI units of standard measurements.

**Calibration Schedules:**

* Purchase each new piece of equipment or instrument according to specifications.
* Place new equipment on an Asset register prior to use.
* Ask the supplier prior to delivery or after installation to calibrate new equipment and provide a certificate of calibration.
* Maintain Calibration / Maintenance schedules for all equipment.

The schedules of calibration or performance checks should be based on:

* Manufacturers recommendations.
* The history of the item as per reliability.
* Reference standards.
* Recalibrate the measuring devices based on time intervals.

 **Reference standards, Traceability and Calibration Limits:**

 **Reference Standards and Trace ability:**

 All measurement standards used to calibrate measuring devices should be traceable to a national standard of measurement either:

* 1. Directly through purchase of pre-calibrated certified standards. These shall be supported by calibration documents or certificate from the supplier stating the date, accuracy (assigned value and units of measure), trace ability and conditions under which the results were obtained. These standards shall be re-calibrated at pre-determined intervals.
	2. Indirectly by preparation of an internal working standard calibrated against a certified standard. These shall be supported by internal test reports and any other supporting documentation.
	3. Where no recognised external standard exists an internal standard may be prepared and calibrated provided a written procedure is prepared and a rationale for assigning values, accuracy and units is established. These standards shall be supported by suitable records of calibration as above.

**Calibration Limits:**

Calibration is concerned with the measurement of values and their comparison with acceptable limits of standards resulting in adjustment or correction, if necessary.

Compare calibration results with established limits for accuracy for the measuring device. If the device being calibrated does not fall within the limits then re-adjust and re-calibrate until it falls within pre-established limits. If not, remove from use.

***The establishment of limits should be based on a combination of:***

* Those specified at the time of purchase.
* Recommendations from the manufacturer.
* Limits established in reference standards.

The acceptable limits required for satisfactory calibration of each instrument should be identified or referenced in the relevant procedure.

**Calibration and Performance Check Procedures:**

Prepare documented procedures based on the instrument manufacturer’s written instructions and use for the calibration and performance checks for all measuring instruments and measurement standards.

***Calibration procedure should include***:

* A list of equipment to which the procedure is applicable.
* Calibration points, environmental requirements and special conditions.
* Limits for accuracy.
* List and identity of traceable standards.
* Sequence of calibration steps.
* Instructions for recording data with reference to the relevant Standard Form.

Performance check procedures should follow a similar format.

**Labelling:**

Label all calibrated equipment with a label that has the following information:

* Date of last calibration.
* Signature of person who performed the calibration.
* Date next calibration due.

Label the equipment that has passed its calibration due date until it is re-calibrated.

**6. DOCUMENTATION:**

Maintain complete records for the calibration and performance checks of all equipment and instruments.

Calibration and Performance Check test records should include(where appropriate):

* Asset Register Number.
* Instrument Serial Number.
* Limits for calibration(refer 4.4.2).
* Date of calibration / performance check.
* Due date for next calibration.
* Any details of adjustment\* or repair.
* Results of the calibration\*/performance check.
* Statement of compliance, or details of non-compliance and action taken.
* Signature/initials of the person performing the calibration/performance check.

\* ***It is important that the results of calibration before and after any adjustment are recorded****.*

Maintain calibration and performance check records for five years.

**7. CORRECTIVE ACTION:**

Conduct a review if any measuring device is found to be out of calibration and requires adjustment. Take corrective action where appropriate.

If the item can be adjusted back into calibration, it may continue to be used. If the item cannot be adjusted back into calibration, it must not be used until the situation is corrected. Under these circumstances attach an identifying label stating that the item is under repair and is not to be used.

The Supervisor must assess the likely impact of the inaccuracy of the affected measurement on the quality of current product and product produced since the previous satisfactory calibration. Factors influencing the degree of risk include:

1. Critical nature of the measurement.
2. Sensitivity of quality control testing to the consequences of the inaccuracy.
3. History of production records and performance checks.

Additional quality control testing may be instituted to determine whether quality has been compromised. Where it is likely that quality has been compromised this shall be communicated to senior management and document reports.

**8. RELOCATION OF INSTRUMENTS:**

Recalibrate the equipment (especially non-portable) when relocated. The manufacturer’s recommendations on the need for re-calibration shall be sought when relocating non-portable instruments.

**9. EXTERNAL CALIBRATION CONTRACTORS:**

Make an agreement with the contractors to supply written reports of calibrations which should include:

* Use of standards and references traceable to national standards.
* Certification/licensing by the equipment manufacturer, if available.
* Check all certificates or reports supplied by approved external laboratories on receipt.

Certificates and reports should contain the same information as mentioned.

* + - 1. **REFERENCES:**
1. Technical Manual of the American Association of Blood Banks – 15th edition 2005.
2. Introduction to Transfusion Medicine – Zarin Bharucha and D.M. Chouhan; 1st Edition, 1990.
3. Training module for laboratory technologists. National AIDS Control Organization, Ministry of Health and Family Welfare, Govt. of India publication, 1995.

**11. END OF DOCUMENT**