**Model SOP**

**Standard Operating Procedure**

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

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| --- | --- | --- | --- | --- |
| **SOP no.** | **Effective Date** | **Pages** | **Prepared by** | **Authorised by** |
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| **Version** | **Review Period** | **Date of Review** | **Reviewed by** | **Number of copies** |
| VI | 2 years | 01-01-2015 |  | 10 |
| **LOCATION** : Quality Assurance Laboratory / Red Cell Serology Laboratory | | | | |
| **SUBJECT** : Equipment Maintenance | | | | |
| **FUNCTION** : Calibration | | | | |
| **DISTRIBUTION**: Quality Assurance Manager / Medical Officer / Supervisor Blood bank  Master File | | | | |

1. **SCOPE & APPLICATION:**

Equipments are integral part of any blood bank and their regular checking and calibrations are important to maintain quality of testing as well as producing blood product. This procedure applies to all the instruments and equipments used within the blood centre.

**2. RESPONSIBILITY:**

It is the responsibility of the supervisor of each laboratory to prepare the maintenance schedules for all equipment items. The schedule is to include preventive and routine maintenance routine.

**3. PROCEDURES:**

***A. GENERAL GUIDELINES***

1- All equipments should be as per specifications

2- Maintenance, periodical servicing & fault repair is needed to process/produce quality products.

3- Each equipment should have a log book.

4- Frequency of testing of any equipment is determined by:

1. Type of equipment
2. Defect in functioning
3. Review of past quality control records

**B.EQUIPMENT MAINTENANCE**

Equipment used for the collection, processing, testing, storage and sale / distribution of blood and its components shall be maintained in the clean and proper manner and so placed as to facilitate cleaning and maintained. The equipment shall be observed, standardized and calibrated on a regularly scheduled on the following basis.

|  |  |  |  |  |  |  |  |  |  |
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|  |  | |  |  |  | | |  | |
|  | ***EQUIPMENT*** | | ***PERFORMANCE*** | ***FREQUENCY*** | | | | ***FREQUENCY*** | |
|  |  | |  |  | |  | | ***of*** | |
|  |  | |  |  | |  | | ***CALIBERATION*** | |
| 1. Temperature | | | Compare against | Daily | |  | | As often as necessary | |
| Recorder | | | thermometer |  | |  | |  | |
| 2. Refrigerated | | | Observe speed and | Each day of Use | | | | As often as necessary | |
| Centrifuge | | | temperature |  |  | | |  | |
| 3.Hematocrit Centrifuge | | | Observe speed and |  | **------** | | | Standardize | |
|  |  | | temperature |  |  | | | beforeinitial use, after | |
|  |  | |  |  |  | | | repair or adjustments, | |
|  |  | |  |  |  | | | and annually | |
| 4. General lab | | | Observe speed and |  | **------** | | | Tachometer, every 6 | |
| Centrifuge | | | temperature |  |  | | | months | |
| 5.Automated Blood | | | Observe controls for | Each day of Use | | | | **------** | |
| typing | | | correct results |  |  | | |  | |
| 6.Heamoglobinometer | | | Standardize against | Each day of Use | | | | **------** | |
|  |  | | cyanamethemoglobin |  |  | | |  | |
|  |  | |  |  |  | | |  | |
| 7. Urinometer, | | | Standardize against | Each day of Use | | | | **------** | |
| Hydrometer | | | distilled water |  |  | | |  | |
| 8.Blood container | | | Standardize against | Each day of Use | | | | As often as necessary | |
| weighing device | | | container of known |  |  | | |  | |
|  |  | | weight |  |  | | |  | |
| 9)Water Bath | | | Observe temperature | Each day of Use | | | | As often as necessary | |
| 10)Rh view box | | | Observe temperature | Each day of Use | | | | As often as necessary | |
| 11 )Autoclave | | | Observe temperature | Each Time of Use | | | | As often as necessary | |
| 12)Serologic rotators | | | Observe controls for correct results | Each day of Use | | | | As often as necessary | |
|  |  | |  |  |  | | |  | |
| 13)Laboratory | | | **------** | **------** |  | | |  | |
| thermometers | | |  |  |  | | |  | |
| 14)Electronic | | | **------** | Monthly | | | |  | |
| Thermometers | | |  |  |  | | |  | |
| 15)Blood agitator | | Pbserve weight of | | Each day of Use | | | Standardize with | |
|  | | the first container of | |  | | | container of known | |
|  | | blood filled or | |  | | | amss or volume before | |
|  | | correct results | |  | | | initial use and after | |
|  | |  | |  | | | repairs or adjustments | |

***C. Important equipment maintenance guidelines***

***Blood Bank Refrigerator***

1- Temperature to be recorded twice daily ( 2-60C)

2- Check alarm system monthly

3- Check uniformity of temperature in upper and lower shelves

4- Maintain temperature record sheet and affix on outside.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | - | - |  |  |
| DATE | TIME | SHIFT | TEMPERATURE | SIGN(STAFF) |

5- Do not open the door of the refrigerator door often.

6- Arrange the blood bags upright so that enough space is for air to circualte.

7- Keep it clean and well lit.

8- Ensure continuous power supply

9- Do not keep any food or drinks.

10- Clean compressor condensor plate with soft cloth every month.

***LAB CENTRIFUGE (SEROLOGY)***

1- Check weekly: Speed (tacho meter)   
 timer (stop watch)

2- Caliberate: Optimum centrufugation time   
 Cell button-well defined edge

***REFRIGERATED CENTRIFUGE***

1- Keep Thermomeler in belween the bags and check temperalure after the

Bags are centrifuged.

2- Use stopwatch to check timeraccuracy.

3- Maintain regular asepsis in between the procedures.

4- Speed check by tachometer

5- Equipment engineer called every 3 months.

***INCUBATORS AND WATER BATH***

1. Check temperature daily
2. Check for insulation and electrical connections
3. Keep water clean ( put thymol crystals to prevent moulds)
4. Culture of waler to be done. (ware baths used for thawing of plasma or cryo)

***BALANCES AND SCALES***

1- Check with known weights while in use or after repairs

1. Caliberate weekly

***MICROSCOPE***

1- Keep covered when not in use

2- Keep coarse adjustment and condensor wellubricated.

3- Clean objectives, condenser and eyepiece with a lens paper frequently.

1. **Maintenance overview:**

* Identify each item of equipment in the unit that requires maintenance. Ensure all items have an Asset Number.
* Include clear outline of the relevant procedures, routine maintenance and preventive maintenance and cleaning of equipment. Write operator instructions for each item of equipment. Also include those responsible and names of service personnel. Maintain a documented log of servicing for all items.
* Identify the relevant procedures for equipment maintenance determine the frequency of calibration and cleaning procedures – clearly identifying the times eg., daily, monthly etc.
* Prepare a complete equipment and instrumentation list consisting of the following headings:
* ***Equipment name / description.***
* ***Asset Number.***
* ***Serial Number.***
* ***Model Number.***
* ***Operation:***
  + Operating Range.
* ***Calibration:***
  + Frequency.
  + Referenced documents.
  + Performed by
* ***Performance Check:***
  + Frequency.
  + Referenced documents.
* ***Preventive maintenance:***
  + Frequency.
  + Referenced documents.
  + Performed by
* ***Routine maintenance***:
  + Frequency
  + Referenced documents.
* ***Cleaning:***
  + Frequency.
  + Referenced documents.
    - Maintain a list of all equipment and instruments used in all sections / departments in the QC lab to ensure all equipment within the department are documented.

1. **Maintenance Schedules:**

Draw up suitable schedules by maintenance type and frequency or by equipment type. Define forward dates for the completion of maintenance and record the date of actual performance in the schedule

1. **Service contracts:**
   * 1. Contracts need to be in place for all equipment items maintained by an external agent.
     2. Each service contract shall define exactly what is carried out / the frequency and by whom it is completed.
     3. At the completion of the service, a maintenance report is to be supplied, signed by the contractor and the officer – in – charge. The report shall detail the work carried out by the contractor.
2. **Repair & breakdown:**
   * 1. Operating instructions for each item of equipment shall identify the steps required to be taken in the event of a fault or breakdown, and shall identify who is responsible for organising service or replacement.
     2. A log book of errors and corrective actions is to be maintained for all equipment items. In the event of equipment breakdown, it is essential that it be clearly labelled and identified as being “OUT OF SERVICE”.
3. **Maintenance overdue:**

The Quality Control Laboratory shall determine the suitability for ongoing use of any equipment that has passed it due date for routine maintenance (where this routine maintenance does not involve calibration). The laboratory must document their reasons for continuing to use an item of equipment that is overdue for maintenance. Where appropriate this should include explanation (and supportive evidence where available) that product quality has not been compromised by this delay in maintenance.

Where possible, documentary evidence from the manufacturer supporting this decision should be provided. Steps should be taken at the next instance of routine maintenance to evaluate whether any discernible damage has been caused to the equipment by the delay in maintenance.

**4. DOCUMENTATION:**

* Maintain individual files of service reports of all equipments.
* Enter the details of all routine as well as trouble-shooting service calls by the manufacturer’s engineer in the equipment maintenance register.
* Maintain a file of all manufacturer’s instructions and where required display them close to the equipment.
* Record the name, address and telephone number of the service engineer to be contacted in case of need.

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

**6. END OF DOCUMENT.**