

GUIDELINES ON MAINTENANCE AND OPERATION OF EQUIPMENT IN A PATHOLOGY LABORATORY (VERSION 1/2004)

College of Pathologists, Academy of Medicine of Malaysia

The guidelines for maintenance and operation of equipment in a Pathology Laboratory include instruments, reference materials, calibrators, reagents, consumables and analytical systems

1. The laboratory shall be furnished with all items of equipment required for provision of services offered by the laboratory
2. All equipment shall be shown to be safe to use and capable of achieving the performance required. Records of evaluation shall be kept
3. The Pathology Laboratory shall ensure that each item of equipment is uniquely labeled and shall maintain an inventory of all equipment
4. The Pathology Laboratory shall maintain a record for each item of equipment which shall include the following:-
 - (i) Identity of equipment;
 - (ii) Manufacturer's name, type, identification and serial number;
 - (iii) Manufacturer contact person and telephone number;
 - (iv) Date of receipt and date of commission;
 - (v) Location of equipment;
 - (vi) Condition when received;
 - (vii) Manufacturer's instruction or reference;
 - (viii) Equipment performance record;
 - (ix) Maintenance record and record of damage, malfunction, modification, and
 - (x) repairs
5. The Pathology Laboratory shall establish a program that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. It shall also have documented and recorded programs of preventive maintenance which at minimum follow the manufacturer's recommendation
6. All equipment shall be maintained in safe working condition.
7. Where a piece of equipment is found to be defective, it shall be taken out of service and clearly labeled, until it has been repaired and shown to function satisfactorily by calibration, verification or testing to meet specified acceptance criteria.
8. All equipment, including hardware, software, reference materials, consumables, reagents and analytical systems shall be safeguarded from adjustments or tampering that might invalidate examination results
9. All equipment shall only be operated by authorized and trained personnel.
10. Only authorized personnel are permitted to undertake handling and disposal of chemical, radioactive and biological materials, which shall be according to manufacturers' specifications.
11. Instructions for the use and maintenance of equipment shall be readily available.

12. Work on high risk group micro-organisms which pose both high individual and community risks shall only be undertaken inside a BSL3 (Bio-safety Level 3) facility.
13. All reagent containers shall be labeled and tightly closed. They shall bear the original label, or as a minimum: reagent name, date of receipt, strength, any special precaution and expiry date. The person responsible for the preparation of reagent shall be identifiable either from the label or from records.
14. Substances that are classified as scheduled poisons under the Poison Act and its Regulations, shall be kept separately from other reagents and held in locked cabinets. These substances shall be handled in accordance to the rules and guidelines contained in the Poison Act
15. When computers or automated examination equipment are used, the laboratory shall ensure that:
 - (a) Procedures are established and implemented for protecting the integrity of data at all time
 - (b) Computer programs and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorized persons

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