17.4: Documentation of laboratory procedures

There should be clear and explicit documentation of all laboratory procedures as SOPs in the laboratory manual, which should be subject to periodic review. The degree to which the documentation is computer-based will depend on local capacity and, to some degree, on the demands of the sponsors. SOPs will help to ensure reproducibility and will facilitate comparisons with results from other laboratories. Logbooks and records should be made for equipment maintenance, the batches of supplies and reagents used at different times, and for the detailed test procedures and the duties and responsibilities of staff members. Certification of staff competencies can also be included. Specific provision should be made for recording unusual events that may affect the results of a test (for example, power failures and fluctuations—though, in some places, these may not be unusual!).

Depending on the size of the laboratory and the variety of tests and procedures undertaken, the documentation should be arranged in a single or several logbooks that are arranged chronologically (World Health Organization, 2009).

4.1 Supplies

One of the sets of laboratory logbooks should provide information on: the reagents, test kits, laboratory equipment (including brand names), the expiry dates of reagents and test kits, storage conditions, batch or lot numbers, specification sheets, and the relevant re-ordering arrangements (for example, when, how much, and by and through whom). A checklist of itemized activities is important to avoid irregular supplies or shortage of reagents and test kits. Regular, at least monthly, inventories and appropriate documentation of all supplies can help to keep track of expiry dates and check on pilferage. Supplies and reagents that have passed their expiry date should never be used. To avoid this happening, a ‘first in first out’ system should be used for issuing reagents and supplies, i.e. the reagents or test kits that are closest to their expiry date should always be issued before the ones that are further from their expiry date. Where Internet access is available, the website addresses and e-mail addresses of suppliers should be recorded.
4.2 Equipment maintenance

Regular checks should be made on each piece of equipment to ensure that it is in good working order. Such checks should be recorded and, for key items, publicly displayed. Some of the items that should be checked regularly are listed in Box 17.3.

In laboratories in the tropics where air conditioning is not available, humidity may lead to problems with both equipment and storage of certain sample types (for example, blood stored on filter paper). In these circumstances, storage with silica gel (as a desiccant) in airtight boxes is appropriate, and the silica gel will require regular (monthly) replacement.

Maintenance procedures are usually described in the instruction booklets for the relevant equipment, but these will need to be augmented with details relating to troubleshooting and contacts of qualified staff or engineers. The complete maintenance instructions for each piece of equipment should be incorporated into a dedicated manual, and a logbook with checklists kept for each piece of equipment. Regular maintenance of certain pieces of equipment may be a prerequisite in some studies. It is important therefore that laboratory staff review these logbooks regularly. It is usually a good idea and cost-effective to have a maintenance contract for all major, complex, and expensive laboratory equipment.

4.3 Procedures and staff duties

Laboratory SOPs, detailing step-by-step instructions for individual procedures, should be collected together in a laboratory manual. The author of each SOP and those staff members who have read it and, where appropriate, been trained in it (and who can therefore perform the procedure) should sign the SOP cover sheet. SOPs will specifically detail to whom staff should report and how they should record results, additional observations, mistakes, and other unusual events. These include, for example, any change of kit or batch number of sera, media, or preservatives. Any changes in assay conditions (for example, changes in incubation time or temperature) will require amendments and updating of protocols, which should be validated by the laboratory supervisor. Staff members involved in distinct sequences of the procedures should be indicated on relevant flow charts, and these should be written into the logbook. A separate staff file, containing details of relevant training and certification, may be warranted in some circumstances.

Box 17.3 Equipment and maintenance: items that should be regularly checked

1. Twice-daily (morning and evening) recording of temperatures of refrigerators, freezers, and cool-rooms, using maxima and minima thermometers and/or digital data loggers where available, should be performed without fail—even on weekends and public holidays! These data should be updated daily on standardized forms to allow easy monitoring of any changes away from the norm.

2. Checking on the position of the cap and the level of nitrogen in liquid nitrogen containers.

3. Regular and systematic inspection of all items of equipment which require clean lenses (for example, microscopes, spectrophotometers) and checks on focus and adjustment of light sources.

4. Periodic checks on the position of centrifuge rotors (tight centre bolts) and regular cleaning. Rotor speeds can be calibrated with an anemometer.

5. Many automated pieces of equipment (for example, haematological and biochemistry analysers) will have self-test and self-calibration programmes that run at start-up and shutdown. The results of these runs should be recorded and archived. More elaborate procedures may be required before and after longer periods of storage without use.
6. Any regularly used field equipment, such as thermometers, portable haemoglobin machines, and other POC diagnostics, will need to be calibrated periodically and have new batches of reagents checked.

7. Regular calibration of routinely used equipment such as balances, pH meters, and variable volume pipettes.

4.4 Unusual or adverse events

The logbook should be used to keep a record of errors in test procedures (operator- or machine-reported) and in the preparation of reagents, power failures, temperature, and humidity changes that might influence the results of the tests or the quality of stored samples. The remedial action taken and results of the rerun of the test should also be documented.