Requirements For Calibration in a Hospital Blood Bank

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1. Introduction

1.1 It is an MHRA requirement that “there are standard procedures for validation and calibration of processes and equipment”. This SOP will consider calibration and provides a basis for meeting this key requirement of the OIG QMS.

1.2 Annex17 of the EEC guide to GMP provides the following definition of calibration “The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standards over an appropriate range of measurements”.

1.3 The EEC guide to GMP includes the following statement in paragraph 3.4.1 “Measuring, weighing, recording and control equipment should be calibrated and checked at defined intervals by appropriate methods. Adequate records of such tests should be maintained”.

2. General Principles

2.1 All instrumentation will be calibrated on a routine planned basis by competent personnel. This may be trained local staff or by external companies, as relevant.

2.2 The following statement will depend on local circumstances (some laboratories use calibration stickers and others chose not to). Where relevant, equipment which is calibrated will be status labelled to indicate the date of calibration, next due calibration and initialled by the person carrying out the calibration.

2.3 The frequency of the calibration shall be agreed with the local manager, and will be based on:

   2.3.1 The criticality of the instrument, or the system it is associated with.
   2.3.2 Industry and regulatory requirements
   2.3.3 The professional assessment of the supplier/manufacturer

   Critical instrumentation will be calibrated every 6 months. Non-critical instrumentation will be calibrated annually.

2.4 Calibration should be carried out within 4 weeks of the target date, otherwise a non-conformance should be raised (incident report should be raised) and consideration given as to whether the equipment should be withdrawn from service.
2.5 Any devices which are deemed not to require calibration shall be status labelled “NOT CALIBRATED – INDICATOR ONLY”

2.6 The tolerances required for each item of instrumentation will be defined as target plus or minus a defined limit. If this limit is exceeded, the instrumentation will need to be adjusted and the significance of the deviation will have to be assessed.

2.7 Calibration of instrumentation will be a key element of the validation of all new equipment or laboratory assays.

2.8 A detailed record of all calibration exercises will be maintained in a laboratory record system which can demonstrate that the defined calibration frequency is being achieved. In addition, calibration will be recorded in a suitable log book for recording all elements of maintenance on the relevant item(s) of equipment.

2.9 A calibration certificate will be provided for the test equipment used to carry out calibration. This certificate must indicate the traceability to the relevant National or International standards. A copy of this certificate will be retained for reference.

3. Calibration Frequencies

A wide range of equipment will include items which require to be calibrated. Examples of Critical instrumentation are as follows

3.1 Temperature probes and chart recorders
   - Critical sensors calibrated to set point +/- 0.5 Deg C
   - Non critical sensors calibrated to set point +/- 1.0 Deg C

3.2 Weighing Equipment
   - Calibration accuracy will depend on the precision of the balance, but the acceptable accuracy will be not more than +/- 0.1%

3.3 Pipettes/ Automated Volume delivery systems
   - Calibration accuracy will depend on the precision of the device, but the acceptable accuracy will be not more than +/- 1%