

supplementary criteria for GLP registration

GLP Compliance Monitoring
Programme

Equipment Calibration and
Traceability of Measurement

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Good Laboratory Practice Compliance Monitoring Programme

Equipment Calibration and Traceability of Measurement

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1 Introduction

1.1 The operation of and general requirements for registration under the International Accreditation New Zealand (IANZ) Good Laboratory Practice (GLP) Compliance Monitoring Programme are detailed in the IANZ publication *Procedures and Conditions of GLP Registration (AS 2)*. In particular, Section 3.2 of that document specifies the registration standards for testing facilities – those being the OECD Principles of Good Laboratory Practice and associated consensus and advisory documents.

1.2 Where there is a need to expand upon or to provide a definitive interpretation of the requirements set out in these registration standards, IANZ will publish Supplementary Criteria for GLP Registration documents. This document, one in the series Supplementary Criteria for GLP Registration, describes the requirements for test equipment calibration and for demonstrating traceability to national or international standards of measurement.

2 Background

Clause 4.2 of Section II of the *OECD Principles of Good Laboratory Practice (1998)* requires that “*Apparatus used in a study should be periodically... calibrated according to Standard Operating Procedures ... Calibration should, where appropriate, be traceable to national or international standards of measurement*”. The following sections outline the requirements that registered facilities will need to demonstrate to meet the New Zealand interpretation of this clause.

The general principle is that the policies adopted are the same as those applied to testing laboratories accredited (to NZS ISO/IEC 17025) by IANZ.

3 Equipment management and calibration

Equipment used in GLP studies and its suitability, ranks on a level equal to the competence of the staff using it. A GLP registered facility will be expected to possess and maintain, under a documented management system, all equipment necessary to carry out the functions for the performance of the types of studies requested for inclusion in the scope of registration.

As required by Clause 4.2 of Section II of the *OECD Principles of Good Laboratory Practice*, this documented management system needs to include:

- (a) Standard Operating Procedures for the conduct of periodic inspection, cleaning, maintenance, and calibration
- (b) A planned programme for the conduct of each of the above for each equipment item
- (c) Maintenance of records for each of these activities.

3.1 Calibration

Calibration involves controlled comparison of the equipment item against a “known” instrument or reference material over the range of values of use of the item to be calibrated. The differences between the “known” instrument and the equipment item under calibration are tabulated for a range of preselected calibration points.

IANZ publishes guidelines on the calibration requirements and calibration intervals for common laboratory items of equipment. These guidelines are published in the Specific Criteria Schedules for each field of testing within the IANZ Laboratory Accreditation Programme. For most GLP registered facilities, the most appropriate documents would be:

- (a) Specific Criteria for Accreditation - *Biological Testing*
- (b) Specific Criteria for Accreditation - *Chemical Testing*

These documents are available free of charge from the IANZ website at www.ianz.govt.nz, or on request from IANZ. If particular items of interest are not listed in these publications, guidance on calibration requirements and calibration intervals can be obtained from IANZ staff.

It should be noted that the published recalibration intervals are generally considered to be the maximum period between calibrations, provided:

- (a) The equipment is of good quality and of proven adequate stability
- (b) The facility has both the equipment capability and staff expertise to perform adequate intermediate checks
- (c) That if any suspicion or indication of overloading or mishandling arises, the equipment is checked immediately and thereafter at frequent intervals until it can be shown that stability has not been impaired.

The maximum calibration intervals have been established by accepted industry practice and international convention. Where the provisions above cannot be met or the operating environment requires a more stringent recalibration period, more frequent calibrations will be expected.

IANZ may accept reduced or require extended calibration intervals based on factors such as history of stability, accuracy required and ability of staff to perform regular checks. It is the responsibility of the facility to provide clear evidence that its calibration system and any changes to an existing system will ensure that confidence in equipment can be maintained.

3.2 Traceability of Measurement

Traceability requires that there is an unbroken chain of equipment whose calibrations to known levels of uncertainty are traceable from one item to the next and eventually to a national standard of measurement. Equally importantly, the concept of traceability also includes the competence of all the people involved, the fitness of each measuring environment, the suitability of the methods used and all other aspects of the quality management systems involved at each step in the chain of measurements.

Traceability must be established for all **critical** measurements and calibrations either:

- (a) Directly to the national standards laboratory or another national body acceptable to the national standards laboratory, or
- (b) To a third party accredited calibration laboratory which is accredited by IANZ or by an accreditation body with which IANZ has a Mutual Recognition Arrangement (MRA).

The calibration certificates issued by accredited calibration laboratories must be endorsed in accordance with the requirements of the accreditation bodies concerned e.g. IANZ endorsement. This constitutes proof of traceability to national standards.

*Note: **Critical** measurements/calibrations are those which will significantly affect the accuracy or proper performance of a study.*

In New Zealand, the national standards laboratory is the Measurement Standards Laboratory of Industrial Research Limited. It recognises other national standards laboratories who are signatories to the CIPM MRA. – see <http://msl.irl.cri.nz> for further information.

Any further queries regarding equipment calibration and traceability of measurement in GLP compliant facilities should be directed to:

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