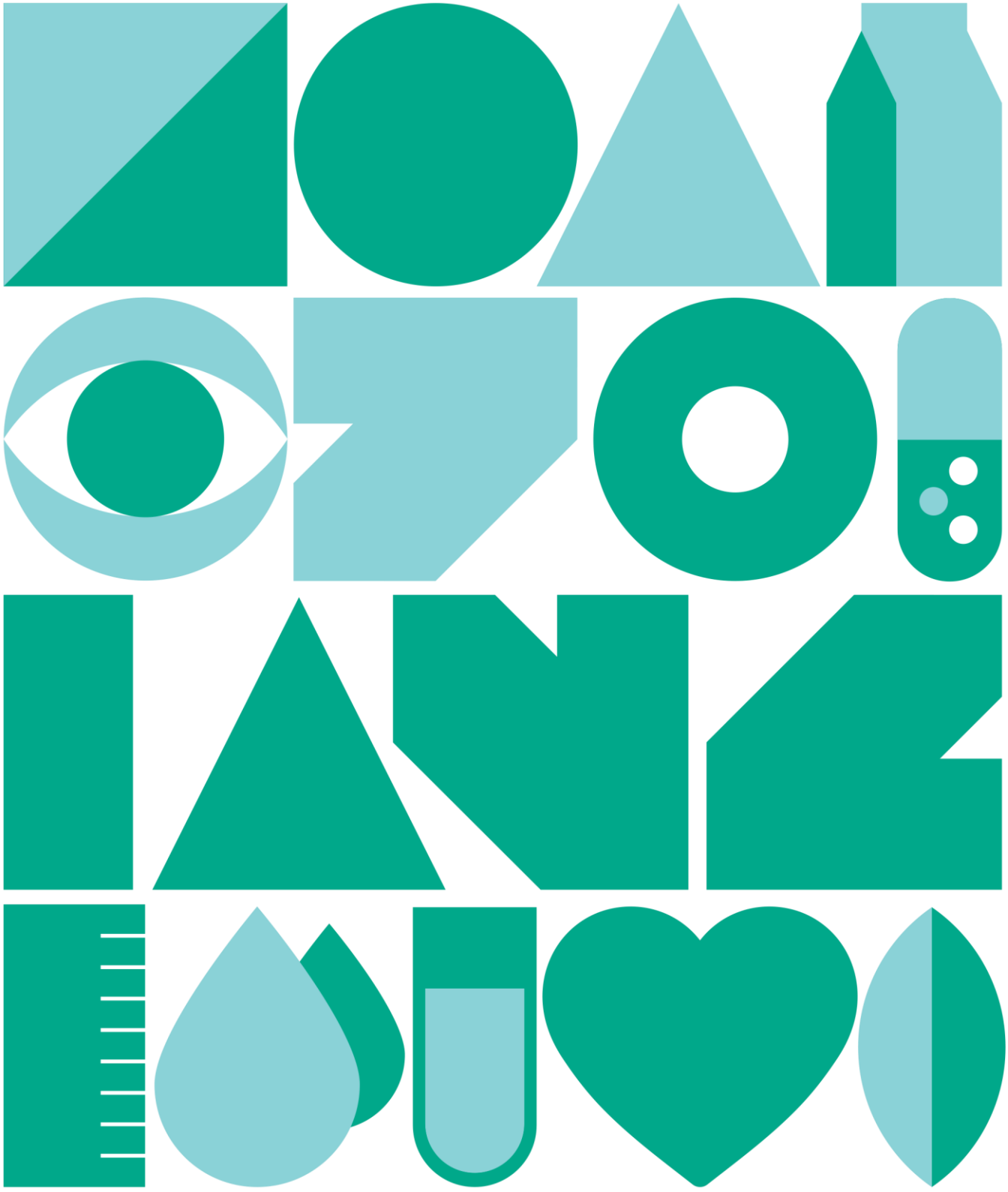

Supplementary Criteria for GLP Registration
Equipment Calibration and Traceability of Measurement

Third Edition July 2020

The NZ mark of competence
Tohu Matatau Aotearoa

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Supplementary Criteria for GLP Registration

Good Laboratory Practice Compliance Monitoring Programme

Equipment Calibration and Traceability of Measurement

AS GLP C20.1

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International Accreditation New Zealand
626 Great South Road, Ellerslie, Auckland 1051
Private Bag 28908, Remuera, Auckland 1541, New Zealand
Telephone: +64 9 525 6655
Email: info@ianz.govt.nz
Internet: www.ianz.govt.nz

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Contents

1 Introduction

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 for 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.

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 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* (AS LAB C1)

(b) Specific Criteria for Accreditation - *Chemical Testing* (AS LAB C2)

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.

The IANZ policy for GLP compliant test facilities to demonstrate traceability to national or international standards of measurement is published in the General Criteria for Accreditation document, *Technical Policy No.1: Traceability of Measurement*, available from the IANZ website.

Traceability must be established for all **critical** measurements and calibrations in accordance with this policy.

Test facilities' attention to drawn to Note 2 in the Technical Policy No.1 document. **Critical** measurements/calibrations are those which have the potential to significantly affect the accuracy, integrity or proper performance of a GLP study. For example, for the types of GLP studies commonly undertaken in New Zealand, traceability to national or international standards of measurement would be expected to be demonstrated for:

- Mass – of test items, analytical sub-samples of test system samples/specimens, analytical standards and the like;
- Temperature – storage and transport of test items and test systems samples/specimens and the like;
- Volume – relating to test item or analytical dilutions and the like.

This list is not exhaustive, and every calibration or measurement undertaken as part of or in support of GLP studies should critically evaluated as to its potential impact on the study conduct and/or outcome.