

Good Laboratory Practice Compliance Monitoring Programme

Procedures and Conditions of GLP Registration

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general criteria for registration

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Scope

The Good Laboratory Practice (GLP) Compliance Monitoring Programme's *Procedures and Conditions for GLP Registration* explains the structure of International Accreditation New Zealand (IANZ) and the procedures and conditions of registration as a GLP compliant facility by IANZ. After briefly introducing IANZ, its history and role in GLP compliance monitoring, Section A overviews the GLP Compliance Monitoring Programme before discussing registration procedures in detail. Section B describes the rights and duties of registered organisations.

Section A: Registration Procedures

1 Introduction

International Accreditation New Zealand (IANZ) is the national authority for the accreditation of testing and calibration laboratories, medical imaging (radiology) services, inspection bodies, and other technical professional services. Its purpose is to underpin and facilitate domestic commerce and external trade through appropriate national conformity assessment and training. It is a not-for-profit Crown entity funded from client fees.

IANZ is the operational unit of the Testing Laboratory Registration Council. The Testing Laboratory Registration Council is a statutory body established by an Act of Parliament in 1972. Prior to 1 July 1997, IANZ operated under the name Telarc New Zealand.

In November 1996, the New Zealand Government instructed Telarc New Zealand (now IANZ) to develop and implement a GLP Compliance Monitoring Programme, and notified the Organisation for Economic Co-operation and Development (OECD) Environment Directorate that IANZ would be the National GLP Compliance Monitoring Authority.

In addition to its GLP compliance monitoring role, IANZ offers accreditation to testing and calibration laboratories, inspection bodies, proficiency testing providers, reference material producers and medical imaging (radiology) practices that meet the relevant technical standards. Close links with other accreditation bodies through the International Laboratory Accreditation Co-operation (ILAC), the Asia Pacific Laboratory Accreditation Co-operation (APLAC) and European Accreditation (EA) ensure IANZ standards are consistently aligned with international expectations.

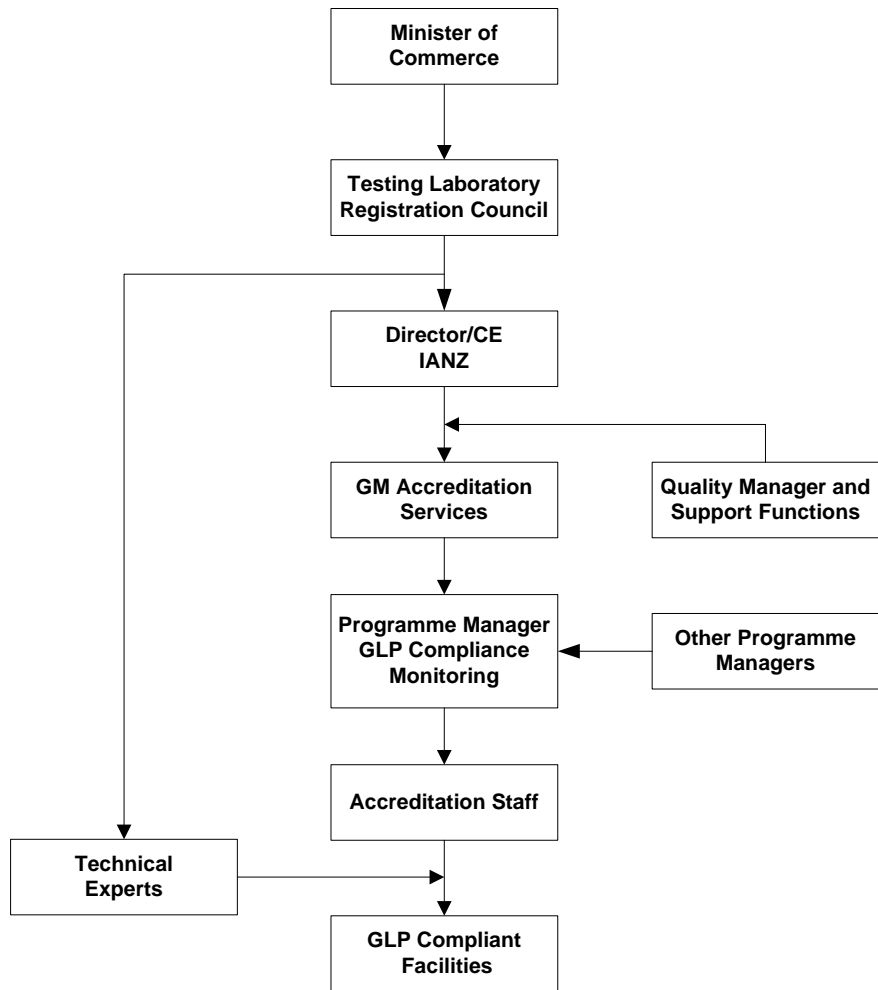
2 Structure

The Testing Laboratory Registration Council's empowering legislation establishes a Council of nine members who are responsible to the Minister of Commerce for administration of its programmes. Five members of the Council are appointed by the Minister and they then appoint a further four members. The Council functions very much as a board of directors, responsible for the broad strategic management of IANZ activities. Day to day management is delegated to the Council's Director, the Chief Executive Officer of IANZ.

Management of the accreditation and GLP compliance monitoring functions of IANZ is the responsibility of the General Manager - Accreditation Services, who is assisted by a team of Programme Managers and Accreditation Assessors. The General Manager, Programme Managers, and Accreditation Assessors all hold appropriate qualifications in science, engineering and technology and are experienced in quality system operation and assessment.

IANZ also maintains a panel of specialist technical experts who are chosen for their personal knowledge and expertise. Technical experts are drawn from the ranks of government laboratories, academic institutions, research associations, industrial organisations and consultancies in New Zealand and overseas. GLP compliance monitoring inspections are normally conducted by an IANZ staff officer alone but from time-to-time a technical expert may be added to the team to determine whether the testing facility's operations comply with GLP compliance criteria.

Organisation Chart



3 Operational Standards

3.1 IANZ Operational Standards

For the conduct of its accreditation programmes, the IANZ operational procedures comply with the requirements of the appropriate international standards, namely ISO/IEC 17011: *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*.

These programmes are subject to regular internal audit as well as external evaluation by overseas accreditation bodies with which IANZ has mutual recognition arrangements. This ensures compliance with these standards.

The GLP Compliance Monitoring Programme's operational procedures also comply in principle with the relevant requirements of ISO/IEC 17011 and also the following OECD Environmental Health and Safety Publications from the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring:
 (a) Number 2: *Guidance for GLP Monitoring Authorities - Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice*

- (b) Number 3: *Guidance for GLP Monitoring Authorities - Revised Guidance for the Conduct of Laboratory Inspections and Study Audits*
- (c) Number 9: *Guidance for GLP Monitoring Authorities - Guidance for the Preparation of GLP Inspection Reports*
- (d) Number 12: *Advisory Document of the Working Group on GLP – Requesting and Carrying Out Inspections and Study Audits in Another Country*

3.2 Registration Standards

Testing facilities registered as being GLP compliant are inspected directly against the requirements of the following OECD Environmental Health and Safety Publications from the Series on Principles of Good Laboratory Practice and Compliance Monitoring:

- (a) Number 1: *The OECD Principles of Good Laboratory Practice* (1998)
- (b) Number 4: *GLP Consensus Document - Quality Assurance and GLP* (1999)
- (c) Number 5: *GLP Consensus Document - Compliance of Laboratory Suppliers with GLP Principles* (1999)
- (d) Number 6: *GLP Consensus Document - The Application of the GLP Principles to Field Studies* (1999)
- (e) Number 7: *GLP Consensus Document - The Application of the GLP Principles to Short-Term Studies* (1999)
- (f) Number 8: *GLP Consensus Document - The Role and Responsibilities of the Study Director in GLP Studies* (1999)
- (g) Number 10: *GLP Consensus Document - The Application of the Principles of GLP to Computerised Systems* (1995)
- (h) Number 13: *Consensus Document of the Working Group on Good Laboratory Practice – The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies*
- (i) Number 14: *Advisory Document of the Working Group on Good Laboratory Practice – The Application of the Principles of GLP to in-vitro Studies*
- (j) Number 15: *Advisory Document of the Working Group on Good Laboratory Practice – Establishment and Control of Archives that Operate in Compliance with the Principles of GLP.*

Number 1 is the primary or base criteria document against which all GLP compliant test facilities are inspected.

These publications are available at no charge at the OECD's web site at <http://www.oecd.org/ehs>

3.3 Supplementary Registration Criteria

In addition to the general requirements for registration detailed in the OECD publications listed in Section 3.2, test facilities will also be inspected against more specific requirements published by IANZ in the GLP Compliance Monitoring Programme: Supplementary Criteria for Registration series of documents.

These are published by IANZ where there is perceived a need to provide a definitive interpretation of the OECD publications.

4 Registration Procedures

4.1 Scope

Any organisation considering obtaining registration as a GLP compliant facility under the IANZ GLP Compliance Monitoring Programme is encouraged to study in detail Section I.1: Scope of the *OECD Principles of Good Laboratory Practice* (Number 1 in OECD Series in Section 3.2 above).

The scope of application of the OECD Principles is restricted to **non-clinical safety testing** of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs, food additives, feed additives and industrial chemicals. The testing of these items **is for the purpose of obtaining data on their properties and/or safety with respect to human health and/or the environment.**

These non-clinical health and environmental safety studies are **intended to be submitted to regulatory or receiving authorities for the purpose of registering or licensing** the pharmaceutical, pesticide, food or feed additive, cosmetic or veterinary drug product or for regulating the industrial chemical.

IANZ will grant a GLP compliance registration only for these types of studies and for the purposes indicated. Other types of trials on test items (such as clinical trials) related to non-safety testing (e.g. efficacy) are outside the scope of application of the IANZ GLP Compliance Monitoring Programme.

4.2 Overview

Once a test facility is satisfied that the OECD Principles of GLP are applicable to the scope of studies it conducts and has written its technical and quality systems to comply with the *OECD Principles of Good Laboratory Practice* and associated consensus and advisory documents (as applicable), an application for registration can be made to IANZ. A schematic overview of the registration procedure is shown in flowchart 4.12.

4.3 Information and Preliminary Discussion

Information about the IANZ GLP Compliance Monitoring Programme is freely available upon request as are copies of the Supplementary Registration Criteria. In addition, IANZ staff are available for advice and assistance.

You may request an advisory visit to your facility (prior to a formal initial inspection) by an IANZ staff member to review your existing systems and procedures and/or to explain registration in more detail. This service is provided at our normal hourly professional fee plus expenses. We can advise on your readiness for the initial inspection and also on any aspects of your GLP quality system that need further development. It also gives IANZ the opportunity to become familiar with your organisation and to advise on the likely scope of your proposed registration.

If your organisation has had no formal contact with IANZ in the past, we strongly recommend such a visit. Our experience suggests that savings will more than recover the cost of an advisory visit in time at the initial inspection.

4.4 Formal Application for Registration

The application fee detailed in the current issue of the relevant IANZ programme fee schedule must accompany applications. Application fees are normally waived if you are a current client in one of IANZ's accreditation programmes.

Before the initial inspection, it is essential that enough background information is provided to IANZ to enable adequate briefing prior to our visit to your facility. The necessary information is requested in the Registration Questionnaire, which accompanies the application and should be returned with it. Some of the important information you need to provide in the questionnaire is:

- (a) The types of non-clinical safety studies conducted at your facility for which GLP Registration is sought. As detailed in the Questionnaire and in accordance with OECD recommendations, these are classified into the following groupings:
 - 20.01 Physical - Chemical Testing
 - 20.02 Toxicity Studies
 - 20.03 Mutagenicity Studies
 - 20.04 Environmental Toxicity Studies on Aquatic and Terrestrial Organisms
 - 20.05 Studies on Behaviour in Water, Soil and Air; Bioaccumulation
 - 20.06 Residue Studies

- 20.07 Studies on the Effects on Mesocosms and Natural Ecosystems
- 20.08 Analytical and Clinical Chemistry Testing
- 20.09 Other Studies.

In addition, the Questionnaire will request further detail on the scope of capability within these groupings for which your facility is seeking GLP compliance

- (b) Key technical staff within your organisation that are called up in the OECD Principles e.g. management, Quality Assurance, Study Directors/Principal Investigators, archivist, etc
- (c) Key Standard Operating Procedures (SOPs) providing the framework for your GLP quality system
- (d) Information on the physical facilities for which GLP compliance is sought, including any remote test sites
- (e) A copy of the master schedule of studies.

Each application is allocated to the Programme Manager (PM) - GLP Compliance Monitoring who will designate an Inspection Co-ordinator (Lead Inspector). The Inspection Co-ordinator will normally review your SOPs against the *OECD Principles of Good Laboratory Practice* to confirm your readiness for an initial inspection. You will receive feedback at this time, and once any major deficiencies in the documentation have been satisfactorily resolved, the Inspection Co-ordinator will arrange with you a suitable date for the on-site inspection.

4.5 Authorised Representative

Each applicant and registered facility must nominate a senior staff member to represent it in all dealings with IANZ. This person is our point of contact with you and is known as the Authorised Representative. All correspondence invoices etc which we send to your organisation will be addressed to the Authorised Representative.

The Authorised Representative may be any senior staff member from either the technical or managerial staff. It is important that they are in a position of sufficient authority to ensure their facility complies with the criteria for registration at all times. There are advantages in nominating a person who is not closely involved in the day-to-day operation of the registration but has authority over it.

If an Authorised Representative resigns or if a facility wishes to replace that person, then IANZ must be informed as soon as possible of the name of the new Authorised Representative.

The Authorised Representative is expected to be present at assessment entry and exit meetings.

4.6 Documentation Review

Before initial inspections and routine re-inspections of your facility, the requested SOPs and supporting documents making up the framework of your GLP system will be reviewed to ensure compliance with the *OECD Principles of Good Laboratory Practice* and applicable consensus and advisory documents. Prior to (particularly for initial inspections) or during on-site inspections, you will be notified of any significant changes needed to your documents.

4.7 Approach to the Inspection

IANZ encourages facilities to consider the positive, helpful elements of the inspection and to regard it as an opportunity for professional, technical and quality management information exchange. The inspectors are not there to find fault, but rather to evaluate your system and to provide helpful, constructive comment and suggestions to enable you to maintain an effective GLP system.

The inspection is a fact-finding exercise undertaken by IANZ staff and, where necessary, by one or more technical experts. When a technical expert is considered to be required, they are acting on behalf of IANZ and do not represent their employer or any other organisation with which they may be associated.

You have the right to veto the use of a particular technical expert proposed for your inspection provided your reasons are valid e.g. conflict of interest.

4.8 The Inspection Procedure

The objective of our inspection is to confirm that you are actually doing what your SOPs say you will and that this is in accordance with the *OECD Principles of Good Laboratory Practice*. During the on-site visit, the inspector(s) will focus on the operation of your GLP system. Information gathered will include, but is not limited to, review of records, discussions with management and key GLP personnel, and observation of relevant activities. A significant element of the inspection will involve study audits - of studies in progress and/or completed studies from the archive.

The time to conduct the on-site inspection will depend on the size of the organisation, the number of individual test sites, the scope or proposed scope of the registration and the number of studies conducted within this (proposed) scope of registration. To date, experience has shown that inspections can take two to three days.

The inspection begins with an entry meeting between the IANZ inspector(s) and senior/key staff of the facility. This entry meeting provides an opportunity for:

- (a) Introductions between the key GLP personnel and the inspector(s)
- (b) Finalisation of the scope of the inspection (considering both number and type of studies conducted and test sites) and a timetable for the inspection
- (c) Resolution of any immediate queries that the inspector(s) or staff may have.

You are asked to provide appropriate guide(s)/escort(s) for each phase of the inspection. These escorts (normally management, Study Directors/Principal Investigators, QA, archivists, etc.) should be senior staff of the organisation who have sufficient authority to ensure the inspectors(s) have access to all documents, personnel and activities they may wish to inspect.

Observations made during the inspection will be recorded on a checklist or notebook. These will include observations of compliance as well as any non-compliance.

Following the information gathering, the inspector(s) will meet in private to review their notes and summarise their findings.

The inspection ends with an exit meeting where your representatives are given this summary, including any areas of non-compliance that have been found and guidance on correcting them. All findings will be fully discussed with you before the inspector(s) leave.

Within ten working days of the inspection, you will receive a comprehensive written report on the inspection findings that were discussed with you at the exit meeting. The report will place the findings into two categories: Corrective Action Requests (CARs) and Recommendations.

- **CARs** are actions that the facility must carry out before registration can be granted or continued. CARs usually relate to non-compliances with the *OECD Principles of Good Laboratory Practice*, applicable consensus or advisory documents and/or Supplementary Registration Criteria publications.
- **Recommendations** are actions that the organisation is urged to carry out in the interests of good practice, but are not considered CARs.

Initial inspections (and likewise for Routine Study Audits and Re-inspections) will result in one of four outcomes:

- (a) No non-compliances (CARs) were identified and registration will be granted/continued following the requisite administrative processes following issue of the formal report.
- (b) A small number of relatively minor non-compliances (CARs) were identified, and registration will be granted/continued following satisfactory provision of documented objective evidence for each CAR by correspondence.
- (c) A relatively large number of non-compliances (CARs) or CARs of a critical or serious nature were identified, and clearance of these CARs by an on-site follow-up inspection by an IANZ staff member is required to effectively verify implementation. The cost of such follow-up visits is charged at the standard rates.
- (d) The test facility is some way from meeting registration criteria and a full initial re-inspection (including documentation review) is required once the facility considers it has addressed the shortcomings.

The test facility will be informed at the Exit Meeting which of the above outcomes applies.

The IANZ inspector will monitor the progress of the test facility in carrying out the required corrective actions. Once satisfied that all conditions for registration have been cleared, a recommendation for registration will be made. Once the Inspection Report(s) and follow-up actions have successfully proceeded through an IANZ internal review process, the IANZ Chief Executive, under delegated authority of the Council, will award registration. A Certificate of Registration will be issued and the name of the test facility together with details of its scope of GLP compliance will be included in the New Zealand Accreditation Directory (at www.ianz.govt.nz). Registration certificates remain the property of IANZ.

Registration allows your facility to make the recommended Study Director's GLP compliance statement in each compliant Study Report. Detailed requirements on the use of this statement are given in the Appendix to this publication.

4.9 Scope of Registration

In a Schedule to the Certificate of Registration, IANZ will detail the scope or types of non-clinical safety studies for which GLP compliance can be claimed under the IANZ GLP Compliance Monitoring Programme.

This scope will be presented under the classification detailed in section 4.4 above, but will include further detail to describe the types of studies that you are properly equipped and sufficiently experienced to conduct. In essence, the scope will attempt to define only those types of studies that you have the demonstrated capability to conduct effectively.

4.10 Routine surveillance inspections

Once you gain registration, your test facility enters the surveillance programme of the IANZ GLP Compliance Monitoring Programme. This programme is designed to ensure that your GLP systems continue to meet the criteria for registration and continue to work effectively. IANZ reserves the right, however, to undertake extra inspections at any time (see 4.11 below).

On the first anniversary (\pm two months) of your initial on-site inspection or any subsequent full initial re-inspection, a Routine Study Audit will be conducted on-site by an IANZ inspector. Experience has shown that many applicants for GLP registration, at the time of their initial inspection, do not have a lot of history of full implementation of the *OECD Principles of Good Laboratory Practice*. In order to be fully satisfied the GLP systems are operating effectively, IANZ considers a Routine Study Audit is necessary once some history of implementation is available. The scope of Routine Study Audits is normally restricted to follow-up of the findings of the initial inspection(s) together with the conduct of one or more Study Audits on completed studies from the archive or studies in progress. However some other elements of the GLP system may be examined at these visits - particularly if there are any changes in personnel or in other key areas.

On the second anniversary of the initial on-site inspection that resulted in registration, and every two years thereafter (\pm three months), a full (routine) re-inspection will be carried out. Routine Re-inspections are similar in their scope, duration and procedures to initial inspections.

For both the Routine Study Audit and Routine Re-inspections, the reporting procedures also resemble those at initial inspections. Once your facility is registered, there is a limit on the time you may take to carry out any requested corrective actions. Once compliance has been demonstrated within the agreed time interval, IANZ formally confirms your continued registration.

You may apply to have your scope of registration changed at any time. If you want to extend the range or types of studies you can carry out, IANZ will usually have to carry out a limited inspection to confirm compliance with the OECD Principles for these types of studies. Such an inspection will be chargeable. If extensions to scope can be delayed until the scheduled re-inspection visit, such extra charges may be reduced.

If Routine Study Audits, Routine Re-inspections or any special inspections conducted (including 4.11 below) reveal that the test facility's systems no longer meet IANZ's criteria for registration, or if the organisation refuses to carry out requested corrective actions either at all or within the specified time, then registration may be suspended or withdrawn.

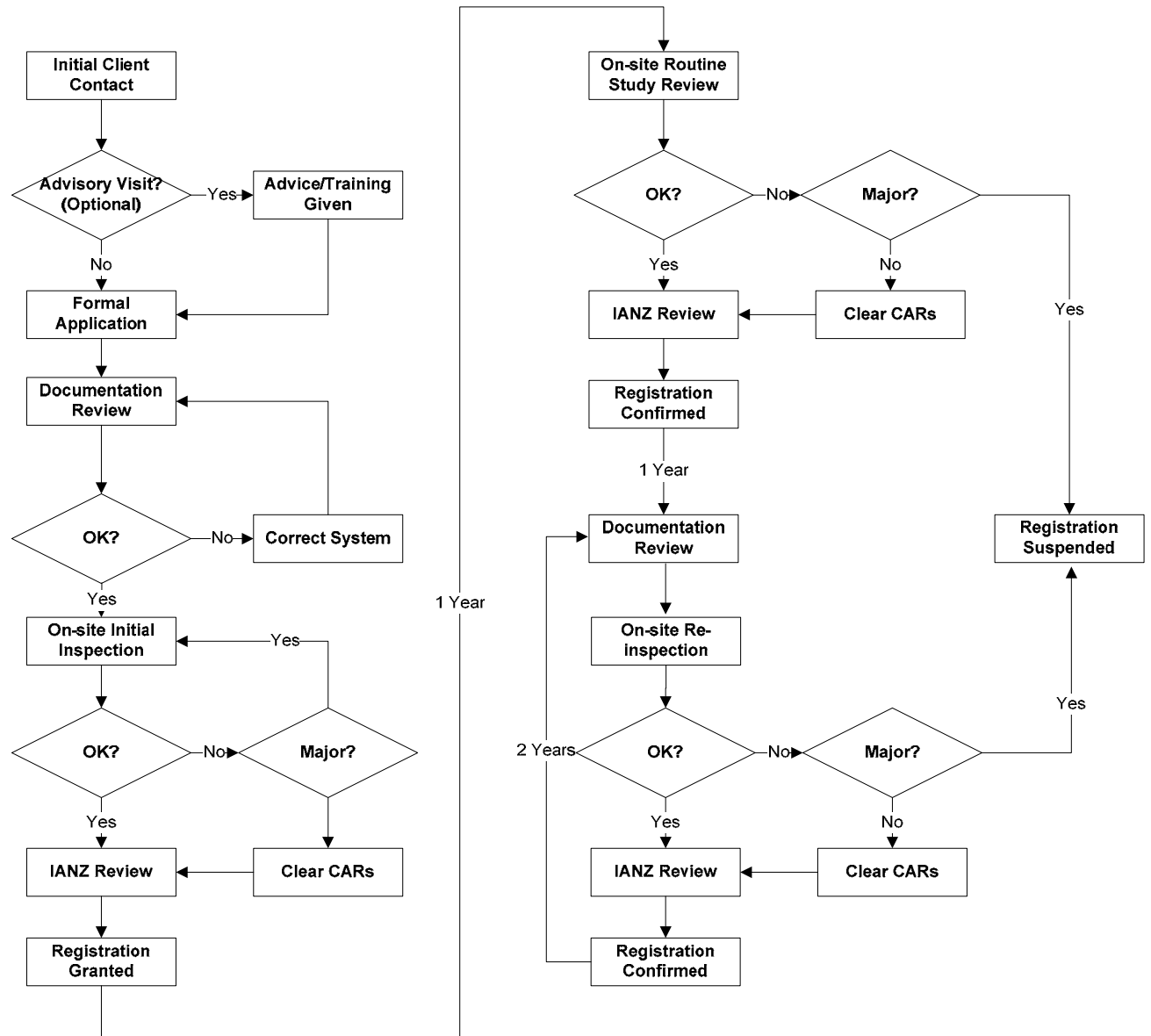
4.11 Special inspection activities

As indicated in 4.10, the test facility can request a special inspection at any time to consider an extension to its scope of registration. Additional special inspections can also be initiated by IANZ under the following circumstances:

- (a) The facility has had a physical change in accommodation that necessitates an on-site inspection to verify registration criteria are being maintained
- (b) Information is brought to IANZ's attention that strongly suggests the registered facility is no longer operating in compliance with the IANZ criteria for registration
- (c) Following a formal request from a regulatory or receiving authority either in New Zealand or from another OECD or OECD-accepted country. Such requests to IANZ would normally arise from particular studies conducted or intended to be conducted at your facility and which are intended to or have been submitted to the requesting receiving authority. The scope of such inspections would likely be restricted to a Study Audit of the particular study in question.

It is possible that IANZ may also be requested to conduct an inspection of a particular test facility or test site by another GLP Compliance Monitoring authority. This would normally apply to multi-site studies where the main test facility is overseas with a particular test site in New Zealand. If the particular test site is already in the IANZ GLP Compliance Monitoring Programme, it is unlikely such an inspection would be required unless there is good reason for doing so. If the test site is not within the GLP Compliance Monitoring Programme, then IANZ would encourage this site to apply and thus be inspected. Such requests from overseas compliance monitoring authorities will be negotiated with all parties involved on a case-by-case basis.

4.12 Inspection Procedures Chart



Section B: Rights and Duties of Registered Facilities

5 Conditions of Registration

5.1 Duties of Applicant and Registered Facilities

- (a) Your facility must have a written quality assurance system that meets all of the requirements of the *OECD Principles of Good Laboratory Practice*, applicable consensus and advisory documents and applicable Supplementary Registration Criteria. Your quality system must operate in the way it is documented
- (b) Your facility must allow our inspector(s) reasonable access to your premises, facilities, resources, operations, procedures, records and staff so that we can effectively inspect your GLP systems and activities
- (c) You must pay all reasonable fees, charges and expenses relating to the initial inspection prior to registration of your facility and to subsequent activity by IANZ regardless of the outcome of those activities. Failure to do so may result in the suspension or withdrawal of your registration, and a requirement for any future fees to be paid in advance
- (d) Your facility must maintain impartiality and integrity in its dealings with clients, with other interested parties and with all those involved in the registered activity
- (e) You may claim to be registered as a GLP compliant facility (or make reference to your registration in any advertising or communication medium) only for work covered by the scope of study types for which you have been registered by IANZ and only if that work has been carried out in accordance with the IANZ criteria. You may not make any statement about your registration that IANZ considers misleading or which is not authorised. You may not use your registration in such a way as to bring IANZ into disrepute
- (f) You must not use your registration to imply approval by IANZ of any product or item you have tested
- (g) You must ensure that the Study Reports you issue (or parts of them) are not used in a way that could mislead your clients or others
- (h) You must notify IANZ promptly of changes in your facility's status or operations such as:
 - (i) loss of key GLP personnel, particularly the GLP management
 - (ii) changes in senior personnel duties and responsibilities (including change of Authorised Representative)
 - (iii) significant changes in accommodation and/or equipment
 - (iv) changes in legal, commercial or organisational status
 - (v) changes in policies and procedures.

Note: If IANZ decides these changes could have affected the compliance of your facility with the registration criteria, then we will carry out an inspection to confirm that you still meet requirements.
- (i) You must not vary the technical operations or facilities covered in the scope of registration during the period between inspections, unless you have given us notice in writing and we have confirmed in writing that such changes do not make your registration invalid

Note: The purpose of this clause is to ensure that no amendments are introduced that will reduce the validity or effectiveness of your operations. It should not restrict the improvements or development of your systems or operations. The size or significance of changes should be considered before IANZ is informed. In any case, IANZ will review all changes at each Routine Study Audit or Routine Re-inspection.
- (j) The use of the IANZ GLP Compliant symbol and/or the terms "GLP (compliant) facility/laboratory", "Registered facility/laboratory" or the like shall be used only under the conditions outlined in Appendix 1. Use of other IANZ logos and/or symbols is not permitted unless you are accredited
- (k) If your registration is withdrawn either by you or by IANZ, then you must immediately stop using the IANZ GLP Compliant symbol and the terms "GLP (compliant) facility/laboratory", "Registered facility/laboratory" or the like, and all advertising material which contains the terms or the symbol or reference to them. Any other documents you have which refer to registration (such as Certificates of Registration or Schedules) must be returned to IANZ or destroyed
- (l) If your facility is temporarily unable to meet registration conditions, IANZ may ask you to stop making any reference to IANZ or the other terms in (k). You will also be asked not to claim compliance with the criteria for registration until we are satisfied that you are again meeting the conditions, or pending the result of any appeal made by your facility.

If your facility fails to comply with such a request, IANZ may:

- (i) Suspend registration, or
- (ii) Withdraw registration, or
- (iii) Decline to grant or renew registration, or
- (iv) Reduce the scope of registration, or
- (v) Decline to extend the scope of registration.

Such decisions and the grounds for them will be communicated to you in writing.

Your compliance with these decisions will be reviewed at Routine Study Audit or Routine Re-inspections.

- (m) IANZ may withdraw or decline to grant or renew registration if your facility becomes bankrupt or makes any arrangements or composition with its creditors, or enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purpose of reconstruction), or has a receiver appointed, or is sold or is taken over. Such decisions and the grounds for them will be communicated to you in writing. In addition, IANZ may require the facility to stop displaying its registration certificate during this period and to refrain from any reference to itself as registered under the IANZ GLP Compliance Monitoring Programme.

5.2 Rights of Applicant and Registered Facilities

- (a) Registration under the IANZ GLP Compliance Monitoring Programme is open to all organisations that come within the scope detailed in Section 4.1 above, regardless of size or professional affiliations
- (b) IANZ will confine its requirements, inspections and registration decisions to the scope of registration requested
- (c) Your application will normally be acknowledged within 10 working days of receipt and you will be sent a receipted tax invoice for the application fee paid
- (d) An estimate of time, costs and expenses (where relevant) for inspection activity will be provided on request. Where a facility is not well prepared for the inspection, the inspection cost may well be higher than the estimate
- (e) We will report the results of each inspection to you within 10 working days of the date of the on-site inspection
- (f) Upon the granting of Registration, IANZ will issue you with a Certificate of Registration and will include in the New Zealand Accreditation Directory the fact that your facility has been granted registration, together with details of its scope of registration. Registration certificates remain the property of IANZ
- (g) IANZ will notify you of any changes in the criteria for registration and give you reasonable time to adjust procedures to meet the new requirements
- (h) Registration is renewable in the first and second years following the granting of registration, and every two years thereafter, subject to your meeting the requirements in 5.1
- (i) You have the right to veto any proposed technical expert who you consider may have a conflict of interest when conducting your inspection
- (j) Complaints or appeals about IANZ can be made to the Chief Executive (see 6 below).

5.3 Confidentiality

We require our staff, technical experts and Council members to abide by a code of ethics, professional standards and confidentiality. They agree in writing to keep information about your organisation confidential and to declare conflicts of interest.

Until you are registered, we will treat your application as confidential. Once you are registered, we will include the scope of your registration in the New Zealand Accreditation Directory.

IANZ, as the National GLP Compliance Monitoring Authority and the designated New Zealand delegate to the OECD Working Group on GLP, has national obligations to fulfil to the other members of the Working Group. One of these involves notification to the other members of the Working Group on studies and facilities that are found not to be in compliance with the *OECD Principles of Good Laboratory Practice*. The purpose of these notifications is to advise the receiving or regulatory authorities of studies that may be submitted as part of registration dossiers and which may potentially be not-in-compliance with GLP.

Where IANZ finds that a registered facility no longer complies with the criteria for registration, registration will normally be suspended (particularly where the integrity of GLP studies undertaken cannot be demonstrated). Such suspensions and an indication of all affected GLP studies already reported will be notified to the OECD and to all members of the Working Group on GLP.

Similarly, where IANZ finds during the course of a study audit that a particular study is not in compliance with GLP and that the integrity of the study has been compromised to an extent as to render it invalid in terms of GLP compliance, this study will be notified to the OECD and to all members of the Working Group on GLP.

On receipt of such notifications, the members of the Working Group (who are all National GLP Compliance Monitoring Authorities) will normally pass these onto the relevant receiving or regulatory authorities in their respective countries. The GLP Compliance Monitoring Authorities and the receiving or regulatory authorities are expected to maintain such notifications in a confidential manner.

5.4 Registration Fees

Registration attracts fees as follows:

- (a) Application Fee
- (b) Assessment Fee (hourly charge)
- (c) Assessment Expenses (at cost)
- (d) Annual Administration Fee.

Current fees are set out in a separate fee schedule, which is available on request.

6 Appeals and Complaints Procedures

Appeals and complaints fall into three categories:

- (a) Appeals about IANZ decisions
- (b) Complaints about the activities of registered facilities
- (c) Complaints about IANZ activities.

If you wish to complain or appeal about our activities or decisions, or the activities of our registered clients, you should put your complaint in writing and send it to the Chief Executive of IANZ. Verbal complaints to the Chief Executive or any other staff member may be acted upon but, by putting the complaint in writing, you can ensure that all relevant information is provided in a logical manner.

6.1 Appeals about IANZ Decisions

An appeal may be made about any IANZ inspection or registration activity, such as:

- (a) Inspection procedure
- (b) IANZ technical decisions including Corrective Action Requests raised
- (c) Suspension of your registration or part of the registration scope
- (d) Withdrawal of your registration.

In the first instance, you should attempt to resolve any technical appeals with the Inspection Co-ordinator (Lead Inspector) or the IANZ Programme Manager – GLP Compliance Monitoring.

When IANZ receives an appeal about a registration decision, the General Manager – Accreditation Services will appoint an appropriate person to investigate it. The investigation will consider whether:

- (a) Current IANZ policies and procedures have been properly followed
- (b) Current IANZ policies and procedures are adequate and appropriate
- (c) Registration decisions have been soundly based on objective evidence.

The result of the investigation and our proposed actions will be reported to you.

If you are not satisfied with our response to your appeal, you should convey this to the Chief Executive of IANZ who will appoint one or more independent persons to review the appeal and make the final decision on behalf of Council. These independent persons will be drawn from the Accreditation Advisory Committee and/or relevant Professional Advisory Committees (see IANZ publication AS1: *Procedures and Conditions of Accreditation*). Please note that these Committee members are also required to abide by the confidentiality arrangements detailed in 5.3 above.

The results of these investigations and decisions will also be reported to you.

6.2 Complaints about Registered Facilities

It is the policy of IANZ that registered facilities are ultimately responsible for the quality of their own services. They should deal appropriately through their own complaints procedures with complaints from customers or competitors.

When we receive a formal complaint about a registered facility e.g. from a customer or a competitor, the Chief Executive will appoint an appropriate person to investigate it. Initially our role will be to assist the complainant and the registered facility to negotiate a satisfactory outcome

At the next inspection, we will investigate the substance of the complaint to determine whether the facility's operations, facilities and procedures continue to comply with the criteria for registration.

If a customer is unable to resolve a quality problem through liaison with the registered facility, this may be taken into account in deciding how soon to make the next re-inspection.

The results of IANZ investigations and our proposed actions will be reported by the appointed person to the registered facility and to the complainant. If either the registered facility or the complainant are not satisfied with the IANZ response, the complaint may be referred by the Chief Executive of IANZ to one or more independent persons for a final decision on behalf of Council in an analogous manner to that in 6.1 above.

The results of these investigations will also be reported to the registered facility and to the complainant.

6.3 Complaints about IANZ activities

Any complaints about the performance or behaviour of IANZ services or staff will be investigated by the IANZ Manager – Quality Improvement on behalf of the Chief Executive using the formal IANZ complaints procedure. You will be advised of the result of the investigation and of corrective action taken.

APPENDIX 1

Rules for the Statement of GLP Compliance

Once registered under the IANZ GLP Compliance Monitoring Programme, Study Directors of the registered test facility are able to make statement in Study Reports claiming compliance of the study to GLP requirements. It is such statements that are sought by most receiving authorities when accepting your study report in support of an application for registration of a product.

The Study Director's compliance statement must be a factual statement and must not be misleading in any way.

The following is the recommended text for a Study Director's compliance statement:

<Name of test facility> holds an International Accreditation New Zealand Registration as an OECD GLP Compliant Laboratory, Registration No. _ _ _

I confirm that all work contained in this report was conducted in accordance with the *OECD Principles of Good Laboratory Practice (1998)* and the terms of Registration of the International Accreditation New Zealand GLP Compliance Monitoring Programme.

Signed:
(Study Director)

Dated:

The text of this recommended wording should be amended only in the circumstances described below i.e. when not all of the Study has been conducted in accordance with GLP requirements.

Rules

- (a) A Study Director's compliance statement together with reference to any of the following terms constitutes an endorsement from IANZ that the organisation (and the study reported) is in compliance with the *OECD Principles of Good Laboratory Practice* under the IANZ GLP Compliance Monitoring Programme:
 - (i) "International Accreditation New Zealand" or "IANZ" or any combination thereof
 - (ii) "Registered", "Good Laboratory Practice/GLP compliant", or any combination thereof.Also, any use of the IANZ name or symbol alone would constitute an endorsement.
- (b) Study Director's compliance statements containing an endorsement from IANZ can be used only by organisations currently registered under the IANZ GLP Compliance Monitoring Programme. This does not include applicant organisation or organisations that have had their registrations suspended or withdrawn at any time during the conduct of the study
- (c) Study Director's compliance statements containing an endorsement from IANZ can be used only for studies within the scope of registration. Where all phases of the study have been conducted in a test facility registered under the IANZ GLP Compliance Monitoring Programme (or in an international GLP compliant facility recognised by IANZ), then the recommended wording of the Study Director's statement detailed above should be used.

If any phase of the reported study has not been conducted in an IANZ – registered GLP compliant facility (or international GLP compliant facility recognised by IANZ), the recommended Study Director's statement will need to be amended to include an appropriate disclaimer e.g.

"I confirm all work contained in this report with the exception of the following phases <list non-GLP phases> was conducted in accordance with...."

Note: Often, and particularly in field studies, some phases are conducted at test sites which exists only for the duration of that phase of the study and which may not have been assessed by the IANZ GLP Compliance Monitoring Programme. GLP compliance for such phases may be claimed only when the conduct of this phase at this site is under the direct supervision of a Study Director or Principal Investigator from the GLP compliant facility i.e. the staff, SOPs, etc are under line control of the management of the GLP compliant facility.

IANZ reserves the right to assess these test sites as part of the registration of the GLP compliant facility.

If the phase of the study has been conducted in another organisation's facilities – that is, whose staff, procedures, operations, facilities, etc are not under line control of the management of the GLP compliant facility nor defined in their management SOPs – then GLP compliance for this phase cannot be claimed if this other organisation is not registered under the IANZ GLP Compliance Monitoring Programme (or equivalent).

In such cases the Study Directors may make factual statements about any other recognition the laboratory may have i.e. accreditation or management system certification. Also, Quality Assurance may list any inspections of the facility it has carried out, but a GLP compliance statement cannot be made. The final acceptance of data from this phase of the study is at the discretion of the receiving authority.

- (d) A Study Director's compliance statement containing an endorsement from IANZ can be made only if at least one phase of the study has been conducted in accordance with the *OECD Principles of Good Laboratory Practice*.

Symbol



- (a) The above symbol of the IANZ GLP Compliance Monitoring Programme may be used in study reports in conjunction with the Study Director's compliance statement. Any use of this symbol in a study report constitutes an endorsement from IANZ of GLP Compliance.
- (b) The symbol may also be used to advertise your registration status as a GLP compliant facility, but such use should not in anyway mislead. Use of the symbol for this purpose must comply with the Conditions for Registration detailed in 5.1 above.

If you use the symbol on your letterhead and/or other corporate stationery, you must not report studies on that stationery unless the report complies with the requirements set out above.