กรมวิทยาศาสตร์การแพทย์
Department of Medical Sciences

Manual for Thailand
GLP Compliance Programme

Bureau of Laboratory Quality Standards
Department of Medical Sciences, Ministry of Public Health, Thailand

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Policy for GLP Monitoring Authority

Bureau of Laboratory Quality Standards (BLQS), Department of Medical Sciences (DMSc) is responsible for recognition of test facilities conducting safety studies for non-clinical health and environmental safety studies, for the purpose of registering and/or licensing pharmaceuticals, food and feed additives, cosmetics products, veterinary drug products and similar products, and for the regulation of industrial chemicals. This is in accordance with the situations and policy of the country to allow the government and private sectors to be able to issue the study results of health and environmental studies to meet the OECD Principles of Good Laboratory Practice which leads to export promotion and public health services throughout the country. The OECD Principles of Good Laboratory Practice are designed to apply to test facilities carrying out health and environmental safety studies on test items under scope of GLP where the results are to be submitted to Regulatory Authorities; national or international bodies with legal responsibility for the registration and licensing of chemicals. From this regard, the National Standardization Council (NSC) has appointed BLQS-DMSc as National Compliance Monitoring Authority to implement the following policy:

(a) Administer the GLP Compliance Programme (GLP CP) and register facilities that meet the OECD Principles of Good Laboratory Practice and the Thai legal and official requirements.

(b) Provide valuable resources to develop the capability of inspector and personnel support the organization.

(c) Cooperate with the Thai regulatory bodies such as FDA and others.

(d) Facilitate international liaison and the continuing exchange of information between GLP Monitoring Authority from other member countries.

(e) Work towards achieving the full membership of the OECD Mutual Acceptance of Data (MAD) in the assessment of chemicals.

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1. Introduction

1.1 Background

The Bureau of Laboratory Quality Standards (BLQS) is government organisation under the Department of Medical Sciences (DMSc) according to the Royal Decree Organizing of the Department of Medical Science, Ministry of Public Health published in Thai Gazette No.126 Section 98ก dated December 28, 2009 (Annex 1). DMSc has been appointed as the National OECD GLP Compliance Monitoring Authority (CMA) by the National Standardization Council (NSC) which is chaired by the Prime Minister (letter No. MOI 0714/31429) dated 29th August 2018. BLQS has been appointed by the director general of the DMSc as the National OECD GLP CMA by letter no. 2703/2561 dated 6th September 2018.

These Principles of Good Laboratory Practice should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals but may be of natural or biological origin, in some circumstances, may be living organisms.

The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment. The position of the BLQS in the organisation structure of the Department of Medical Sciences is presented in the organisation chart. (Annex 2)

As National Compliance Monitoring Authority, the BLQS has adopted the OECD Principles of GLP. The structure, policies and procedures under which BLQS operations are documented to ensure implementation of these policies and procedures are administered in an independent and impartial manner to ensure the smooth operation of all compliance activities. The GLP Compliance Monitoring Programme is integrated in the BLQS as one of the operation unit under GLP CMA section. (Annex 3). Cooperation with other national GLP CMAs may include carrying out inspections of test facility/study audit on the request of local/international Regulatory Authority (RA) and foreign GLP CMA.

The Compliance Monitoring Program for inspection of BA/BE studies for GLP Compliance was established in 2007 and terminated in September 2018. The Compliance Monitoring Program for inspection of non-clinical safety studies started on September 2017.

1.2 The BLQS is committed:

- To administer its policies and procedures in a non-discriminating manner.

- To enforce procedures to monitor the compliance of inspected test facilities in order to maintain impartiality and integrity.

- To assure its decision on inspection to those matters specifically related to the scope of the considered inspection.

- To assure that the BLQS employees and inspection are properly trained, exhibit public service at their best and are free from any commercial, financial and other under pressure, with might skew the inspection process.

- To assure that the BLQS shall maintain compliance, consistency, transparency and integrity in its daily conduct and when fulfilling its obligations.

- To assure maintenance of confidentiality when applicable.

- To assure allocation of resources to implement its quality related policies and procedures.

- To cooperate with the Thai regulatory bodies.

2. Objective

The manual describes the quality management system of the BLQS as one of the National Compliance Monitoring Authority (CMA) for monitoring compliance to Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP). This manual is supplemented by relevant forms, OECD documents and BLQS Requirements.

The objectives of this manual are to explain the following:

1) Policies and procedures of BLQS for GLP Compliance Programme (GLP CP).
2) Mechanism for test facilities entering into the GLP CP.
3) Process on the conduct of inspection on test facilities and study audit.
4) Process of exchanging information with other national CMA according to the provisions of OECD GLP and reporting of the inspection and study audit.

3. Scope

The BLQS GLP Compliance Programme is voluntary programme offer to test facilities conducting studies for non-clinical health and environmental safety studies on test item contained in products in the following categories:

1) Pharmaceuticals
2) Pesticides
3) Cosmetic products
4) Veterinary drug products
5) Food additives
6) Feed additives
7) Industrial chemicals products
8) Others

The testing of these items is for the purpose of the non-clinical safety testing of test items is to obtain data on their properties and/or their safety with respect to human health. Non-clinical health safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory. Type of studies/areas of expertise on test items subjected to the BLQS GLP CP are in the following categories:

1) Physical-chemical testing
2) Toxicity studies
3) Mutagenicity studies
4) Environmental toxicity studies on aquatic and terrestrial organisms
5) Studies on behavior in water, soil and air; bioaccumulation
6) Residue studies

7) Studies on effects on mesocosms and natural ecosystems

8) Analytical and clinical chemistry testing

9) Other studies

4. Definitions of Terms

4.1 Good Laboratory Practice (GLP)

4.1.1 Good Laboratory Practice: A quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

4.2 Terms concerning the organisation of a Test Facility

4.2.1 Test Facility: The persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multi-site studies, those which are conducted at more than one site, the test facility comprises the site at which the Study Director is located and all individual test sites, which individually or collectively can be considered to be test facilities.

4.2.2 Test Site: The location(s) at which a phase(s) of a study is conducted.

4.2.3 Test Facility Management: The person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these Principles of Good Laboratory Practice.

4.2.4 Test Site Management (if appointed): The person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these Principles of Good Laboratory Practice.

4.2.5 Sponsor: An entity which commissions, supports and/or submits a non-clinical health and environmental safety study.

4.2.6 Study Director: The individual response for the overall conduct of the non-clinical health and environmental safety study.

4.2.7 Principle Investigator: An individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibility for delegated phases of the study. The Study Director's responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable Principles of Good Laboratory Practice are followed.

4.2.8 Quality Assurance Programme: A defined system, including personnel, which is independent of study conduct and is designed to assure Test Facility Management of compliance with these Principles of Good Laboratory Practice.

4.2.9 Standard Operating Procedures: Documented procedures, which describes how to perform tests or activities normally not specified in detailed in the study plan of test guidelines.

4.2.10 Master Schedule: A compilation of information to assist in the assessment of workload and for tracking of studies at a test facility.

4.3 Terms Concerning the Non-Clinical Health and Environment Safety Study

4.3.1 Non-clinical health and environmental safety study, henceforth referred to simply as "study", **:** An experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or safety, intended for submission to appropriate regulatory authorities.

4.3.2 Short-term study: A study of short duration with widely used routine techniques.

4.3.3 Study plan: A document, which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

4.3.4 Study plan amendments: An intended change to the study after the study initiation date.

4.3.5 Study plan deviation: An unintended departure from the study plan after the study initiation date.

4.3.6 Test system: Any biological, chemical or physical system or a combination thereof used in a study.

4.3.7 Raw data: All originally test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period.

4.3.8 Specimen: any material derived from a test system for examination, analysis, or retention.

4.3.9 Experimental starting date: The date on which the first study specific data are collected.

4.3.10 Experimental completion date: The last date on which data are collected from the study.

4.3.11 Study initiation date: The date the Study Director signs the study plan.

4.3.12 Study completion date: The date the Study Director signs the final report.

4.4 Terms Concerning the Test Item

4.4.1 Test item: An article that is the subject of a study.

4.4.2 Reference item (control item): Any article used to provide a basis for comparison with the test item.

4.4.3 Batch means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

4.4.4 Vehicle means any agent, which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the test system.

4.4.5 Software (application): A program required for or developed, adapted or tailored to the test facility requirements for the purpose of controlling processes, data collection, data manipulation, data reporting and/or archiving.

4.4.6 Software (operating system): A program or collection of programs, routine and sub-routine that controls the operation of a computer. An operating system may provide services such as resource allocation, scheduling, input/output control and data management.

4.4.7 Source code: An original computer program expressed in human-readable form (programming language), which must be translated into machine-readable form before it can be executed by the computer.

4.4.8 Validation of computerised system: The demonstration that a computerised system is suitable for its intended purpose.

4.5 Terms concerning to Compliance Programme

4.5.1 GLP Principles: Principles of Good Laboratory Practice that are consistent with the OECD Principles of Good Laboratory Practice.

4.5.2 GLP Compliance Monitoring: The periodic inspection of test facilities and/or auditing of studies for the purpose of verifying adherence to GLP Principles.

4.5.3 (National) GLP Compliance Programme: The particular scheme established by a Member country to monitor good laboratory practice compliance by test facilities within its territories, by means of inspections and study audits.

4.5.4 (National) GLP Monitoring Authority: A body established within a Member country with responsibility for monitoring the good laboratory practice compliance of test facilities within its territories and for discharging other such function related to the good laboratory practice as may be nationally determined. It is understood that more than one such body may be established in a Member country.

4.5.5 Test Facility Inspection: An on-site examination of the test facility's procedures and practices to assess the degree of compliance with GLP Principles. During inspection, the management structures and operational procedures of test facility are examined, key technical personnel are interviewed, and the quality and integrity of data generated by test facility are assessed and reported.

4.5.6 Study Audit: A comparison of raw data and associated records with the interim or final report in order to determine whether the raw data have been accurately reported, to determine whether testing was carried out in accordance with the study plan and Standard Operating Procedures, to obtain additional information not provided in the report, and to established whether practices were employed in the development of data that would impair their validity.

4.5.7 Lead Inspector: A person who has been trained on OECD Principles of GLP, to lead and responsible for the inspection conducted on behalf of Bureau of Laboratory Quality Standards.

4.5.8 Inspector: A person who has been trained on OECD Principles of GLP and performs the Test Facility Inspections and Study Audits on behalf of Bureau of Laboratory Quality Standards.

4.5.9 Expert: A person who has knowledge in their specified area i.e. computerised system, toxicology etc.

4.5.10 GLP Compliance Status: The level of adherence of a test facility to the GLP Principles as assessed by the (National) GLP Monitoring Authority.

4.5.11 Regulatory Authority: A national body with legal responsibility for aspects of the control of chemicals.

5. Abbreviation

OECD	**:**	The Organisation for Economic Co-operation and Development
FDA	**:**	Food and Drug Administration
DMSc	**:**	Department of Medical Sciences
BLQS	**:**	Bureau of Laboratory Quality Standards
GLP	**:**	Good Laboratory Practice
CMA	**:**	Compliance Monitoring Authority
CP	**:**	Compliance Programme
SOP	**:**	Standard Operating Procedure
WS	**:**	Worksheet
F	**:**	Form
QA	**:**	Quality Assurance Programme
IC	**:**	In Compliance
NIC	**:**	Not In Compliance

6. Requirements for Test Facility

6.1 The test facility must be legal identifiable. The test facility may comprises permanent test facilities, with or without sites away from its permanent.

6.2 The test facility shall implement the management system according to the OECD Principles of Good Laboratory Practice. Associated consensus and advisory documents should be implemented as applicable.

6.3 The top management of the test facility or the authorized representative shall sign the application.

6.4 Each applicant must nominate a senior staff member to represent it in dealing with BLQS, DMSc. The authorized representative may be a senior technical or managerial staff who holds an appropriate position in the organization with the authority to ensure their facility complies with the criteria for registration at all times. The authorised representative is expected to be present at staring and closing conference.

6.5 The application shall be submitted with the detail of the GLP management system and the implementation document, which can fulfill the requirements of the BLQS. The controlled release of such documentation to BLQS is the responsibility of the test facility wishing to enter the BLQS GLP Compliance Programme. The BLQS will terminate the application if the documents are not completed within 180 days, after the date of submitting the application, where appropriate.

6.6 The test facilities shall comply with the registration procedure and shall pay fee schedule as scheduled and conditioned by the BLQS, DMSc.

6.7 The Test Facility shall obligate with the inspectors in the following;

6.7.1 Permit the access to the premises, facilities, resources, operations, procedures, records and staff.

6.7.2 Prepare for the evidences during on-site inspection according to the request of the Inspectors, including the hand on analysis for witness.

6.7.3 Prepare the test sample and evidence for the inspection.

6.7.4 Provide the room for examination of document, the meeting of Inspector team and other activities.

6.7.5 Assist and allow the use of the office stationary and the communication apparatus as necessary.

7. Management System

The BLQS is appointed to be a National CMA by the National Standardization Council which has the Prime minister acting as the chair of committee (The appointment letter no. MOI 0714/31429 dated 29th August 2018) for all studies area of expertise as mention in the scope. The director of BLQS is responsible for GLP compliance programme and the GLP CMA section carries out the daily operations.

As the BLQS CMA has adopted the OECD GLP Principles The structure, policies and procedure under which BLQS operates are document to ensure implementation of these policies and procedures are administered in an independent and impartial manner and also to ensure the smooth operation of all compliance activities. The BLQS management system has been established, documented, implemented and maintained to give confidence in its ability to operate the compliance process in an effective manner.

The publication of documents relating to the adoption of GLP principles within its territory including CMA manual, SOPs and Forms, inspection reports and other related documents develop by BLQS CMA.

Cooperation with other GLP CMA may include carrying out inspections of test facility/study audit on the request of local/international Regulatory Authority and foreign GLP CMA.

The BLQS is directly responsible for an adequate team of inspectors having the necessary technical/scientific expertise or is ultimately responsible for such a “team”. Details are described in the personnel and training section of the manual.

Test Facility Management is also reminded that legislation exists which controls the use of animals in experiments. Test facilities should follow the Animal for Scientific Purpose Act, B.E.2558 (A.D.2015).

Structure of Organisation

The Director General of Department of Medical Sciences as the head of Department who transfer his power on this GLP compliance programme to the Director of BLQS as describe in letter no. 2703/2561 dated 6th September 2018.

The director of BLQS is responsible for overseeing the operation of all accreditation and GLP compliance programme including regional and international accreditation/compliance

matters. The organisation chart of the DMSC and BLQS are as shown in (Annex 2) and (Annex3) respectively.

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8. Confidentiality

The BLQS manual procedures provide adequate arrangement consistent with the GLP principle to safeguard confidentiality of the information obtained in the course of its compliance monitoring activities at all levels within the organisation. This arrangement is to protect confidentiality encompasses all members including inspectors/experts, Appeal Panels, GLP officer and individuals acting on behalf of BLQS CMA.

- BLQS CMA maintains a high level of confidentiality in its operations. It ensures this by obtaining signatures of commitment is confidentiality and independence from inspectors and experts.

- Unless all commercially sensitive and confidential information has been excised, full reports of Test Facility Inspections and Study Audits are made available only to Regulatory Authorities if so requested by the Regulatory Authority, and where appropriate, to the test facilities inspected or concerned with Study Audits and/or to study sponsors. Inspectors and other persons who gain access to information related to GLP Compliance Monitoring are required to sign a contract incorporating appropriate confidentially clauses *(F 07 15 023: Confidential, Financial and Conflict of Interest Statement)*.

9. Personnel and Training

9.1 The BLQS should ensure that an adequate number of competent inspectors are appointed to carry out Inspections and Study Audits. The inspection will be led by a lead inspector that is responsible for the conduct of inspection, starting conference, report findings and closing conference. Inspectors/experts assigned will perform Test Facility Inspections and Study Audits wherever necessary. The names of the inspectors/experts and their organisation will be maintained in BLQS CMA inspector database.

9.2 The competence of an inspector is determined based on education, relevant work experience and training in GLP inspection. The inspector candidate shall have degree in a recognized academic institution. In addition, the candidate shall have practical experience in the range of scientific discipline to the testing chemicals under the GLP Compliance Programme. The candidate shall be appointed as a trainee inspector by the Director of BLQS based on recommendation by the GLP Manager upon satisfactory evidence provided show fulfillment of the education and work experience requirements.

9.3 The trainee inspector is to undergo a GLP inspector training programme. (i) The first part of the training programme includes at least one GLP course or workshop organized by OECD or national/international GLP Compliance Monitoring Authority on GLP for inspector programme. The aim is to equip the trainee inspector with a comprehensive knowledge of the requirements and implementation as described in the OECD GLP document series, inclusive of the principles, guidance, consensus, test guidelines and managerial skills in communication, planning, organizing, conducting and reporting of the inspection/study audit. The training may include the leadership skills in chairing opening and closing meetings, heading the inspection/ audit, dealing with conflicts and decision-making. (ii) The aim of the second part of the GLP

inspector training programme is to equip the trainee inspector with appropriate skills and attribute for conduct of GLP inspection. The training shall be in form of observation and/or performing inspection under supervision of an assigned inspector or a lead inspector. A trainee inspector shall be considered for appointment as a GLP inspector after completing at least 30 hours of observation or supervised inspections/ or study audits and recommended by the assigned inspector or lead inspector based on the satisfactory evaluation following SOP 07 15 022: Monitoring and training of GLP inspector.

9.4 The BLQS can appoint a person to the position of GLP inspector or GLP lead inspector, without the person going through the GLP inspector training programmes as described in respective sections above, if the person has already attained the necessary pre-requisites, i.e. high-level education, relevant working experience, comprehensive knowledge in GLP documents, trained in GLP inspection/study audit, and managerial and leadership skills in auditing. The appointed GLP inspector is to be evaluated during the first inspection.

9.5 The BLQS can appoint the experts contracted who have knowledge of the OECD Principles of GLP and should be scientifically and academically qualified in the studies to be audited.

9.6 A person is authorized to carry-out the job function of a BLQS GLP inspector or GLP lead inspector only after the appointment letter has been signed by the BLQS director which recommend by GLP manager.

9.7 The GLP inspectors shall participate in seminars, training courses, workshops, attachments, observations etc. for continuous improvement of their knowledge and skill related to the inspection/study audits techniques and scientific knowledge of area of expertise of test facilities.

9.8 The GLP Manager should regularly monitor the performance of the GLP inspectors and GLP lead inspectors as or when necessary to ensure the inspector capability or at least once a year.

9.9 The inspectors have to identify inspector’s card which issue by director of BLQS to the test facility during inspection programme.

10. The National GLP Compliance Programme

10.1 General

The BLQS as a National GLP Compliance Programme is intended to ascertain whether test facilities have implemented requirements as described in documents of OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring recommendation. The GLP Compliance Programme includes pre-inspection, full inspection/study audit, and extra ordinary inspections (where applicable). The inspection process is demonstrated in the flow chart as in Annex 4.

The BLQS will conduct Test Facilities Inspections/Study Audit for compliant test facilities for the first years after granted and then continue for routine inspection every two years in accordance with the GLP compliance programme. If no GLP study has been conducted within two years since the last inspection, a suspension for minimum 12 months will be given. Test facility should advise the BLQS as soon as possible that GLP study is to be performed. Hence, the BLQS will conduct Test Facility Inspection/Study Audit in order to reinstate the suspension status. If there is no action taken by test facilities within 6 months. The BLQS will remove the test facilities from GLP Compliance Programme. The BLQS may also remove test facilities from the GLP CP in the right of:

a) Failure to comply with GLP CP requirements as stated in this manual;

b) Failure to provide cooperation or facilities for BLQS, its inspectors and/or its Authorized representatives to discharge their official duties;

c) Fraudulent practices, which include but not limited to; deception of claims and alteration of GLP certificate;

d) An individual or sole proprietorship test facilities is declared bankrupt or enter into composition with his creditors; or

e) Compliant test facilities, being a company, enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purposes of reconstruction) or enters into receivership.

The BLQS CMA shall maintain a Master Register which containing information on the name of test facility, the date of inspection, scope, the area of studies/expertise, compliance status and remarks. These manual and relevant documents used in the programme are prepared by designated personnel, reviewed by GLP Manager and approved by Director of BLQS.

10.2 The Mechanisms by which Test Facilities enter the programme

The GLP Compliance Programme is voluntary. At Test Facility can enter the national GLP Compliance Programme either at the request of the facility itself or at the request of national or foreign Regulatory Authorities or at the request of foreign Monitoring Authorities or by means of a notification to the Receiving Authority which obliges Test Facilities claiming compliance with GLP.

The applicant shall pay for the registration fee. Fees are determined according to categories as mention in 11.4. The test facility wishing to enter the BLQS GLP Compliance Programme has to submit supporting documents containing background details on the organisation and the scope of its activities relevant to compliance facility with the OECD Principles of GLP as follows:

1. Form no.5 (F 07 15 025): Applications form for GLP compliance test facility.
2. Form no.6 (F 07 15 026): Detail of specific information for GLP compliance test facility.
3. Form no.7 (F 07 15 027): Self-evaluation complying with OECD Principles of Good Laboratory Practice
4. Location maps of the Test Facility and nearby landmark building.
5. Organogram.
6. Copy of the official company registration bored the authorized personnel names.
7. Copy of trade registration or the commercial license.
8. Power of attorney.
9. Copy of house registration and identification of the applicant.
10. Nomination a senior staff member as a representative in all dealing with BLQS, DMSc.
11. Layout plan of the testing facilities.
12. Master schedules of all completed and on-going studies.
13. Full set of SOPs (include list of SOPs)
14. List of equipment.
15. Quality Manual or Site Master File or other names.
16. Study plan and Study report
17. List of personnel and Curriculum vitae
18. 3 CDs or thumb drives contain all informations 1-17.

Application form can be download from http://blqs.dmsc.moph.go.th

The controlled release of such documentation to BLQS is the responsibility of the facility wishing to enter the BLQS GLP Compliance Programme. All documents will have complete check by GLP officer using *WS 07 15 021/01: GLP application review* within 15 working days. The BLQS will terminate the application if the documents are not completed within 180 days after the date of submitting the application, where appropriate. Before initial inspection and routine inspection of the facility, the facility's SOPs and supporting documents making up the framework of the GLP system will be reviewed to ensure compliance with the OECD Principles of Good Laboratory Practice and applicable consensus as well as advisory documents. Test facilities shall have at least **one completed study and one on-going study** that has been conducted in compliance with the OECD GLP principles, assigning of test facility registration as follow *SOP 07 15 030: Assignment test facility registration and code number*.

In case of sub-contract inspectors, The BLQS will make an approach letter to a qualified lead inspector and inspectors to conduct inspection of those test facilities within the time frame. If those inspectors agree to take responsible for inspection, then he/she have to sign in *Consent of acceptance as inspectors (F 07 15 022).* After that, the BLQS will ask for acceptable from the test facility via email or letter and test facility have to confirm the appointment or if the test facility considers that a problem of confidentiality or commercial interest then they can arise with the presence of one or more members of the inspection team a demand for replacement can be sent. The arguments for replacement have to be addressed in writing to the director of BLQS within 15 working days after received.

The BLQS will appoint the inspectors team and defined date for evaluation following *SOP 07 15 024: Appointment of inspector*. All the relevant documents with the test facility inspection will transfer to the inspector after they sign in *Confidential, Financial and Conflict of Interest Statement Form (F 07 15 023)*

Before the date of inspection, the BLQS will inform test facility about definite date and agenda for at least 15 working days following form *F 07 15 082: Agenda and Notification of GLP pre-inspection/F 07 15 078: Agenda and Notification of GLP inspection*.

11. Categories of Test Facility Inspection and Study Audit

11.1 Pre-inspection

Pre-inspections are carried out if the Test Facility has to be inspected for the first time. Pre-inspection will be conducted within 90 working days upon receiving completed application document. A pre-inspection is normally carried out within one day to familiarize the inspector team with the management structure, the physical layout of buildings, the documentation system and the ranges of studies of the test facility following (*SOP 07 15 027: Pre-inspection*). The pre-inspection schedule will be informed to the test facility by letter at least 15 working days before date of inspection. Such documents shall provide information on:

- the type, size and layout of the test facility;
- the master schedule
- the management structure of the test facility including CVs, job description of key personnel
- at least one study plan/protocol for completed study

It is absolutely necessary that Test Facility Management or Authorized Representative, Archivist and QA staffs are present at the pre-inspection. During pre-inspection, documents and records may be asked and copied for inspection.

The Authorized Representative is expected to be present at starting and closing conference for the GLP inspection. All participants have to sign in the form: *F 07 15 051: Starting and closing conference for GLP inspection*. The inspector team shall be informed to the test facility by the Director of BLQS. Appropriate experts may be cooperated in some cases in order to conduct an effective study audit.

The pre-inspection starts with an opening session at which the inspector outlines the purpose and the scope of the visit. This introduction will be followed by a management's presentation concerning the organisation and the activities of the test facility. Some premises of the test facility will be visited whereby the overview of activities such as the type and separation of activities, the environmental conditions and the identification and storage of apparatus, test systems, test and reference items and archives are observed. During this visit, the normal work could be slightly disturbed.

The result arising from the pre-inspection shall be presented in a report (*WS 07 15 027: GLP Pre-Inspection Report and F 07 15 034: Record of inspection*). It is usual practice that initial verbal suggestion is given on conclusion of a pre-inspection then record in summary. After that, the BLQS shall send the official pre-inspection report to test facility within 15 working days. Test facility should take appropriate corrective actions with regard to the deviations observed before full inspection. The inspection is programmed within 6 months till 12 months from the closure of pre-inspection finding. If the test facility is still not ready for the inspection within 12 months, the BLQS will consider performing a new pre-inspection or remove from the programme.

11.2 Full Inspection/Study Audit

The inspection process should be involved for both Test Facility Inspection and Study Audit. The procedure for carrying out all type of inspection and study audit according to *OECD No.3: The Revised Guidance for the Conduct of Laboratory Inspections and Study Audits.* The criteria described in the OECD Consensus and Advisory Documents shall also be taken into consideration during the test facility inspections and study audits where appropriate. Inspection and study audit of one or more on-going and at least one completed studies on a sampling basis should be conduct for at least 2-5 working days depending on number of studies conducted by test facility. The length of the inspection can be extended during the inspection with one or more days depending upon the size of the Test Facility and the number of study directors and GLP studies to be audited, or in case of unforeseen workload.

The team consists of a lead inspector and inspector or experts (where necessary). The inspection programme will be informed to the test facility by writing at least 15 working days before a date of inspection. Agenda includes the date and time of inspector's arrival, the composition of inspection team and the items to be inspected and schedule duration of inspection.

It is absolutely necessary that Test Facility Management or its representative, Study Director and QA staff are present at the starting and closing conference. During the inspection, the test facility should assign appropriate personnel to accompany the inspectors. As far as possible, the lead inspector inspects the general operation of the test facility whereas the Study Audit is conducted by the inspection team. During the inspections, inspectors may interview study director, study personnel and archivist of the test facility. In some particular cases documents or records may be asked and copied of evidence. Test facility shall make available a room for examination documents and other activities by the inspectors.

The inspection will start with meeting between the inspector(s) and test facility personnel. The purpose of the starting conference is to inform the purpose and the scope of the inspection and to identify the test facilities areas, study selected for audit, documents and personnel involve in inspection process. Thereafter, test facility management or test facility representative is asked

to give a general presentation about the organisation and the activities of the test facility. All participants have to sign in the form: *F 07 15 051: Starting and closing conference for GLP inspection.* The inspection team will not be concerned with the scientific design of the study, or the interpretation of the findings of the studies, with respect to risk for human health or the environment. These aspects are the responsibility of those Regulatory Authorities to which the data are submitted for registration/ licensing purposes.

During the inspection, if any of observations of non-compliance as well as some deviations seen, the inspector shall discuss in private meeting and review their notes and summarize their findings as in form *1) F 07 15 034: Record of inspection*, 2) Checklist form, *WS 07 15 021/03: GLP inspection checklist*, and 3) making on-site report as form, *F 07 15 036: On-site Report of Inspection/Study Audit*. When serious or major deviations are observed, the lead inspector can decide to stop the inspection earlier than planned

When inspection has been completed, the inspector should discuss his/her findings with representative of the test facility at a closing conference and prepare a written report. Within 15 working days of the visit, a written report on the inspection findings will be sent the test facility. The inspection report is completed by the lead inspector, in accordance with OECD document *No.9, Guidance for the Preparation of GLP Inspection Report, (1995)*. The findings are classified as follows *(Refer to OECD No. 2 Page 13- classification of findings):*

- Deviation, the evidence which is not in compliance with the principles of GLP. The deficiency seriously influences the good functioning of the GLP quality system or the integrity of study data. (Refer to 12.2 Classification of deviation)

- Observation, the evidence which does not have serious impact on the functioning of the GLP quality of the integrity of data.

The test facility will be informed of the possible outcomes. These outcomes may be:

(a) In Compliance with GLP–No deficiency was identified and registration will granted/continued following satisfactory provision of documented objective evidence for other deficiencies (if any).

(b) Not in Compliance with GLP – The test facility is unable to meet the Principles of GLP and it is required that a follow-up inspection be conducted after it has addressed the deficiencies.

All the finding is written down in report on inspection in *WS 07 15 023/01: Report on inspection of test facility/ SOP 07 15 023*: *Preparation of inspection report* which is signed and dated by the inspectors and handed over to the Test Facility Management. Test facility shall finish correction in the timeframe for major and minor deviation according to 12.2

All details of conducting test facility inspection and study audit was mentioned in *SOP 07 15 031: The conduct of test facility inspections and study audit.*

Note: Routine-inspection will be conducted at the first year after date of granted. The next inspection will be conducted every 2 years based on last granting date. Test facility shall apply for inspection at least 120 days before the expiry date. A full inspection will be carried out within 90 working days.

11.3 Extra Ordinary Inspection

The following are other circumstances that may require inspections as listed below but not limited to:

- **Follow up inspection**: If a Test Facility Inspection or Study Audit reveals deviations from the GLP Principles, the test facility will be required to correct deviations and provided written evidences to the BLQS GLP officer. The corrective action shall be submitted within 30 working days. The inspector may propose verification of corrective action on-site, when required. If the test facility cannot complete the corrective action on time, the BLQS shall decide to remove the facility from GLP Compliance Programme.
- conduct of inspection or study audits on the request of national or international authority: Specific Study Audits may also be requested by a foreign CMA or local/international Regulatory Authorities. Such requests may sometimes involve Test Facility Inspections. However, it is the responsibility of the Regulatory Authority or the foreign CMA to identify and justify the need of such Inspections and Study Audits.
- extension of new area of expertise
- significant changes in the test facility (e.g changes of address, relocation, renovation etc)
- others where necessary.

11.4 Fees

Registration attracts fees as follow:

Documentation Review Fee	Baht 10,000 per one application
Inspection Fee	
Lead inspector	Baht 2,000/day
Inspector	Baht 1,500/day/person
Expert	Baht 1,000/day/person
Transportation, accommodation and daily allowance where necessary	
Registration certificate fee	Baht 25,000/one application
Extension fee for routine inspection	Baht 10,000/one inspection
Extension fee for extending scope	Baht 10,000
Annual fee	Baht 2,000
Extra or replacement of registration certificate	Baht 2,000

12. Inspection report and Approval

12.1 Inspection Report

The inspection team will prepare a written report and submit to the test facility after the closing conference.

12.2 Classification of Deviation

During the inspection, the inspection team may come across areas/issues which are not in compliance with the OECD Principles of GLP, BLQS GLP CP and Test Facility's procedure. Such deviations are classified into following categories.

Major deviation:

Major deviation is defined as deviation from the GLP Principles, BLQS GLP CP and Test Facility's procedure that threatens the integrity of quality system and/or study data.

a) When major deviation is observed during inspection, appropriate corrective action shall be taken by the applicant. The corrective action period shall not exceed 30 working days from the last date of inspection, but another delay of 30 working days can be permitted for the first time applicant if test facility can justify the delay. The applicant shall not receive compliance certificate until corrective action has been handled satisfactory and accepted by inspection team. In case if the test facility fails to take satisfactory actions within the specified time, the BLQS may consider verification inspection or removal from the programme.

b) When major deviation is observed during Routine inspection/ Follow-up inspection process the test facility would be given an opportunity to make appropriate measures within a specified time frame of 30 working days, to resolve the issues. In case if the test facility fails to take satisfactory actions within the specified timeframe, the BLQS may remove the test facility from the programme. If corrective action is not submitted within the timeframe, the lead inspector will make recommendation to GLP manager and then report to Director of BLQS whether part or entire part of test facility or part or entire part of study is declared as non-compliant and remove from the program. The test facility is given 15 working days to response to the Director of BLQS. The BLQS GLP officer will be informed about this decision according to existing provisions of OECD GLP. Once the test facility is removed from the programme, the test facility can re-enter into the programme by submitting a new application. The BLQS will consider whether it is necessary to conduct pre-inspection or an inspection can be conducted directly.

Action will be taken by the BLQS CMA where serious are found: as follow:

- Issuance of a statement, giving details of the inadequacies or faults found which might affect the validity of studies conducted in the test facility;
- Issuance of a recommendation to a Regulatory Authority that a study be rejected;
- Suspension of Test Facility Inspections or Study Audits of a test facility and, for example and where administratively possible, removal of the test facility from the (National) GLP Compliance Programme or from any existing list or register of test facilities subject to GLP Test Facility Inspections;
- Requiring that a statement detailing the deviations be attached to specific study reports;
- Action through the courts, where warranted by circumstances and where legal/ administrative procedures so permit.

Minor deviations:

During the Inspection and/or Study Audit, the inspector may come across areas/issues that do not pose threat either to the quality of GLP system or to integrity of raw data. Such deficiencies are normally observed in isolated areas.

a) When minor deviation is observed during inspection, appropriate corrective action shall be taken by the applicant. The corrective action period shall not exceed 90 working days from the date of last inspection. The applicant shall not receive compliance certificate until corrective action has been handled satisfactory and accepted by inspection team.

b) During the follow-up inspection process, the test facility will be given 30 working days to take action of such deviations. However, if the test facility fails to take satisfactory action within the duration mentioned, then the BLQS will remove it from the programme.

Observation:

During the inspection, findings which are not recorded as not in compliance with the OECD Principles of GLP. The BLQS GLP CP and test facility's procedure, are raised as observation for the reasons as follows:

a) An area of concern but unable to obtain sufficient objective evidence

b) An opportunity for test facility to consider possible improvement.

12.3 Final approval of inspection reports

The lead inspector and team will review and/or accept the corrective actions submitted by test facility within 15 working days. The inspection team will sign in the inspection report *(WS 07 15 023/01: Report on inspection of test facility)* with approval from lead inspector and then send to the BLQS CMA. Then, the GLP manager will check all document, prepare the recommendation form *(WS 07 15 03: Recommendation for GLP registration by BLQS)* and send it to the director of BLQS to make a final decision within 15 working days. For test facility found to be in compliance, the Director of BLQS will grant/continue GLP compliance Annex 5: Certificate of Compliance to OECD GLP and a notification *(F 07 15 083: Letter of Statement of Compliance)* will be issued to the test facility.

12.4 Status of GLP Compliance

There will be two categories of compliance status given to test facilities namely;

(a) in compliance [ic] and

(b) not in compliance [nic]

The BLQS will issue a certificate with statement of GLP compliance to show the test facility has been inspected and found to be operating in compliance with Principles of GLP once inspection report completed.

12.5 Withdrawal of the registration

12.1 Withdrawal of the registration *(SOP 07 15 025: Withdrawal of Registration)*

The BLQS will withdraw the registration under the following circumstances.

12.1.1 The test facility is declared bankrupt from courts.

12.1.2 Functions of an organization do not fulfil GLP Compliant and/or the BLQS's requirements and conditions of the registration that have affected on the study results or the test facility service or the GLP Monitoring Units.

12.1.3 Test facility discontinues its functions.

12.1.4 Test facility could not complete a correction within a given time period.

12.1.5 An officially request by the test facility.

13. Appeals and Complaints

Appeals and complaints fall into two categories

- Appeals on registration decision *(SOP 07 15 026: Complaint of Registration)*

- Complains on registration and inspection activities

13.1 Appeal on Registration Decision

An appeal may be about a registration activity, such as withdrawing of registration. Problems or differences of opinion between inspectors and test facility management will normally be resolved during the inspection or at the exit meeting. However, where problems persist and agreement on differences cannot be reached during the inspection process, the test facility management may appeal the findings of the GLP Inspector. Appeal against the findings of the GLP Inspectors and disputes concerning the interpretation of the OECD Principles of Good Laboratory Practice, should be submitted in writing to the Director of BLQS within 15 days after the notice is officially informed. The Director of BLQS will then take appropriate steps to achieve a mutually acceptable resolution. Therefore he/she may ask for advice of the GLP manager, independent internal or external experts and make the decision. The test facility aggrieved by any decision of the Director of BLQS may make a written appeal to Director General of DMSc who the chairman of the Ad hoc appeal committee within 30 days after receipt of decision. The Director General will appoint three independent persons to review the appeal and make the final decision on behalf of the Ad hoc Appeal Committee. These independent persons will be drawn from the Food and Drug Administration, Ministry of Public Health and /or Department of Agriculture, Ministry of Agriculture and Cooperatives, and/or The Thai Industrial standards Institute (TISI), Ministry of Industry and /or relevant Professional Association. External experts may be co-operated and when required. They also should be trained on OECD Principles of Good Laboratory Practice and shall be required to sign an undertaking for maintaining confidentiality *(F 07 15 057: Undertaking of Confidentiality)*.

This decision would be taken after considering the test facility appeal against the decision of the Director General. The decision of the Ad Hoc Committee shall be made within 90 days period or when appropriate in a manner consistent with the Bureau of Laboratory Quality Standards' criteria. During the appeal process, the status of test facility is identified as withdrawal then the final status is defined by the appeal committee.

13.2 Complaints on registration and inspection activities

Complaints from Test Facility is defined as expression (written, or by electronic media), of discontent or accusation addressed to the BLQS *(WS 07 15 026/01: Complaint of Registration)*. It may be discount or accusation aimed at the BLQS staffs or experts acting on behalf of the authority and which is relevant to performance or behavior of BLQS service. The complaint handling system is managed by GLP manager. The BLQS has been reporting on Complaint Log Form *(WS 07 15 026/02: Complaint Log Form)*. For resolution, a time interval is set for 60 days. However, dealing with a complicate one may need more than 60 days. The result of the investigation and of corrective action taken will be reported to the complainant.

14. Right and Duties

14.1 Application under the GLP Compliance Programme is open to all organisations that come within the scope detailed in Clause 3 above, regardless of size or professional affiliations.

14.2 The BLQS archives the original of the final reports. A copy of them is sent to the test facility and to the Regulatory Authority concerned. Foreign CMA could request the final report of TF of concerned if any doubt or more explanation required for register in their country.

14.3 Upon the granting of registration, the BLQS will issue test facility with a Certificate of Registration and will include registration details of the facility in the website.

14.4 A test facility has the right to veto any proposed inspectors/experts whom the test facility considers may have a conflict of interest at the initial appointment before conducting the inspection.

14.5 Complaints or appeals can be made to GLP officer.

14.6 The test facility must allow inspectors and observers reasonable access to the premises, facilities, resources, operations, procedures, records and staff so that the inspectors can effectively assess the GLP systems and activities.

14.7 If loss of key personnel, particularly the Test Facility Management and the infrastructure of the test facility, or the areas of expertise conducted is significantly extended or changed, the test facility has the obligation to inform these changes to BLQS within 15 working days.

14.8 The test facility must promptly pay all fees, charges and expenses relating to the initial inspection, registration of facility and any subsequent activities by BLQS regardless of the outcome of these activities. Failure to do so may result in the withdrawal of the registration.

14.9 The test facility must not make any statement about its registration to mislead the public. The facility must not use the registration in such a way as to bring BLQS into disrepute.

14.10 The Test Facility must not use the registration to imply approval by BLQS of any product or item from the Test Facility.

14.11 The registration may be withdrawn either by the test facility or by BLQS. The test facility must immediately stop making reference to terms “GLP (compliant) facility/laboratory”, “registered facility/laboratory” or the like, and all advertising materials which contains the terms or refers to them.

15. Communication and information

BLQS cooperates closely with relevant receiving authorities such as DOA (pesticides) and FDA (pharmaceuticals) and informs them on the results of inspections by issuing the copies of annual overviews. In order to facilitate the communication between sponsors, test facilities, national or foreign Regulatory and foreign Monitoring Authorities, the BLQS can provide information on inspections to the interested parties in three forms:

- The conclusions of GLP inspection and a "Statement of GLP compliance", where the inspection reveals adequate compliance with GLP, are given to the Test Facility. This information will also be made available on request to the national or foreign Regulatory Authorities concerned.

- The list of GLP compliant test facilities shall be available on website http://blqs.dmsc.moph.go.th

- Annual overview of GLP monitoring report including the Test Facilities inspected and their GLP status shall be submitted to the OECD Secretariat annually (Annex 6).

16. Archives

There are two types of documents that shall be archived:

16.1 Documents related to BLQS GLP Compliance Monitoring Programme.

- The manual of BLQS GLP Compliance Monitoring Programme
- All procedure and forms
- Records of qualification and experience, training and job descriptions of inspectorate personnel.
- Other GLP documents, if appropriate

The BLQS will retains the above records at a designated area for at least 5 years

16.2 Documents generated during the process related to GLP inspection of the test facilities.

- Documents of correspondence with local / international regulatory authority or CMA
- Relevant notes taken during the course of inspections and study audits

All documents related to GLP inspection of test facilities are stored and retained in the archives for at least 10 years except for inspection reports and /or summary reports will be keep as long. Only the authorized personnel can access to the documents maintained in BLQS locked archive. One original hard copy of quality document of applicant will be returned to them after issued the certificate and other one will be retained at BLQS. BLQS retains those document in hard copy or CD or external drive.

Test facility is recommended to retain all documents and records related to GLP Compliance for at least 6 years. Before dispose or discarding the records or documents after 6 years, communication with sponsor need to be recorded.

17. Reference

The manual was prepared based on current documents of OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. These documents are regularly reviewed; therefore the user of this manual should also refer to the OECD for updated version. In cases where contradictory interpretation or elaboration arises between this manual and OECD series, the OECD series would be considered as final.

OECD Series of documents that were referred where relevant in preparation of this manual are as follows:

1. OECD Principles of Good Laboratory Practice, 1998.

2. Guidance for the GLP Monitoring Authorities Procedures for GLP, 1995.

3. Guidance for the Conduct of Laboratory Inspections and Study Audit, 1995.

4. Quality Assurance and GLP, 1999.

5. Compliance of Laboratory Suppliers with GLP Principles, 2000.

6. The Application of the GLP Principles in field studies, 1999.

7. The Application of the GLP Principles to short-term studies, 1999.

8. The Role and Responsibility of the Study Director in GLP studies, 1999.

9. Guidance for the preparation of GLP Inspection Reports, 1995.

10. The Application of the Principles of GLP to Computerised Systems, 1995.

11. Advisory document of panel on the GLP: Role and Responsibility of the Sponsor in the Application of the Principles of GLP, 1998.

12. Advisory document of the Working Group on GLP: Requesting and Carrying out Inspections and Study Audits in another country, 2000.

13. Advisory document of the Working Group on GLP: The Application of the OECD Principles of GLP to the Organisational and Management of Multi-Site Studies, 2002.

14. Advisory document of the Working Group on GLP: The Application of the OECD Principles of GLP to in-vitro studies, 2004.

15. Advisory document of the Working Group on GLP: Establishment and control of Archives that Operate in Compliance with the Principles of GLP, 2007.

16. Advisory document of the Working Group on GLP: Guidance on the GLP Requirements for Peer Review of Histopathology, 2014.

17. Advisory Document of the Working Group on GLP: Application of GLP Principles to Computerised System, 2016.

18. OECD Position Paper Regarding the Relationship between the OECD Prinicples of GLP and ISO/IEC 17025, 2016

19. Advisory Document of the Working Group on good Laboratory Practice on the Management, Characeterisation and Use of Test Items, 2018.

Whenever new documents are published by the OECD relevant to Good Laboratory Practice, they should be read and complied accordingly.

Related documents in Standard Operating Procedure

SOP 07 15 022: Monitoring and training of GLP inspector.
- WS 07 15 022/01: Monitoring Inspector's Performance

SOP 07 15 023: Preparation of Inspection Report
- WS 07 15 023/01: Report on Inspection of Test Facility

SOP 07 15 024: Appointment of Inspector
- WS 07 15 021/02: Document sending for test facility inspection and study audit
- WS 07 15 021/04: Document for inspection
- F 07 15 022: Consent of acceptance as inspectors
- F 07 15 023: Confidential, Financial and Conflict of Interest Statement

SOP 07 15 025: Withdrawal of Registration
- WS 07 15 025/01: A Subject for Withdrawal of Registration.
- WS 07 15 025/02: Report of Withdrawal of Registration.
- WS 07 15 025/03: Declaration of Withdrawal of Registration.

SOP 07 15 026: Complaint of Registration
- WS 07 15 026/01: Complaint of Registration
- WS 07 15 026/02: Complaint Log Form

SOP 07 15 027: Pre-Inspection
- WS 07 15 027: GLP Pre-Inspection Report
- F 07 15 034: Record of inspection

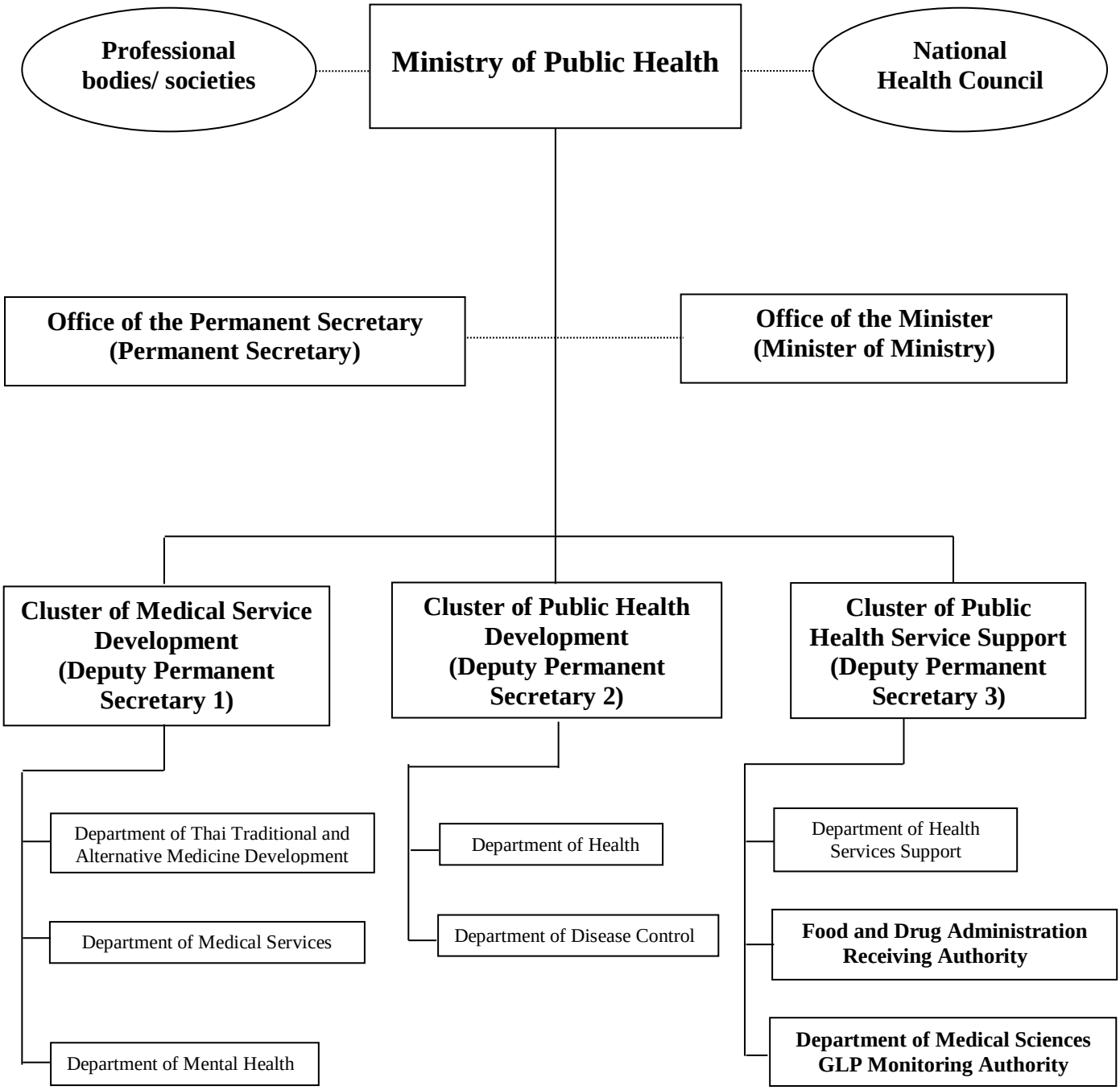
SOP 07 15 030: Assignment test facility registration and code number

SOP 07 15 031: Conduct of Test Facility Inspections and Study Audits
- WS 07 15 021/03: GLP Inspection Checklist
- WS 07 15 023/01: Report on inspection of test facility
- WS 07 15 031: Recommendation for GLP registration by BLQS
- F 07 15 034: Record of inspection
- F 07 15 036: On-site report of inspection/study audit

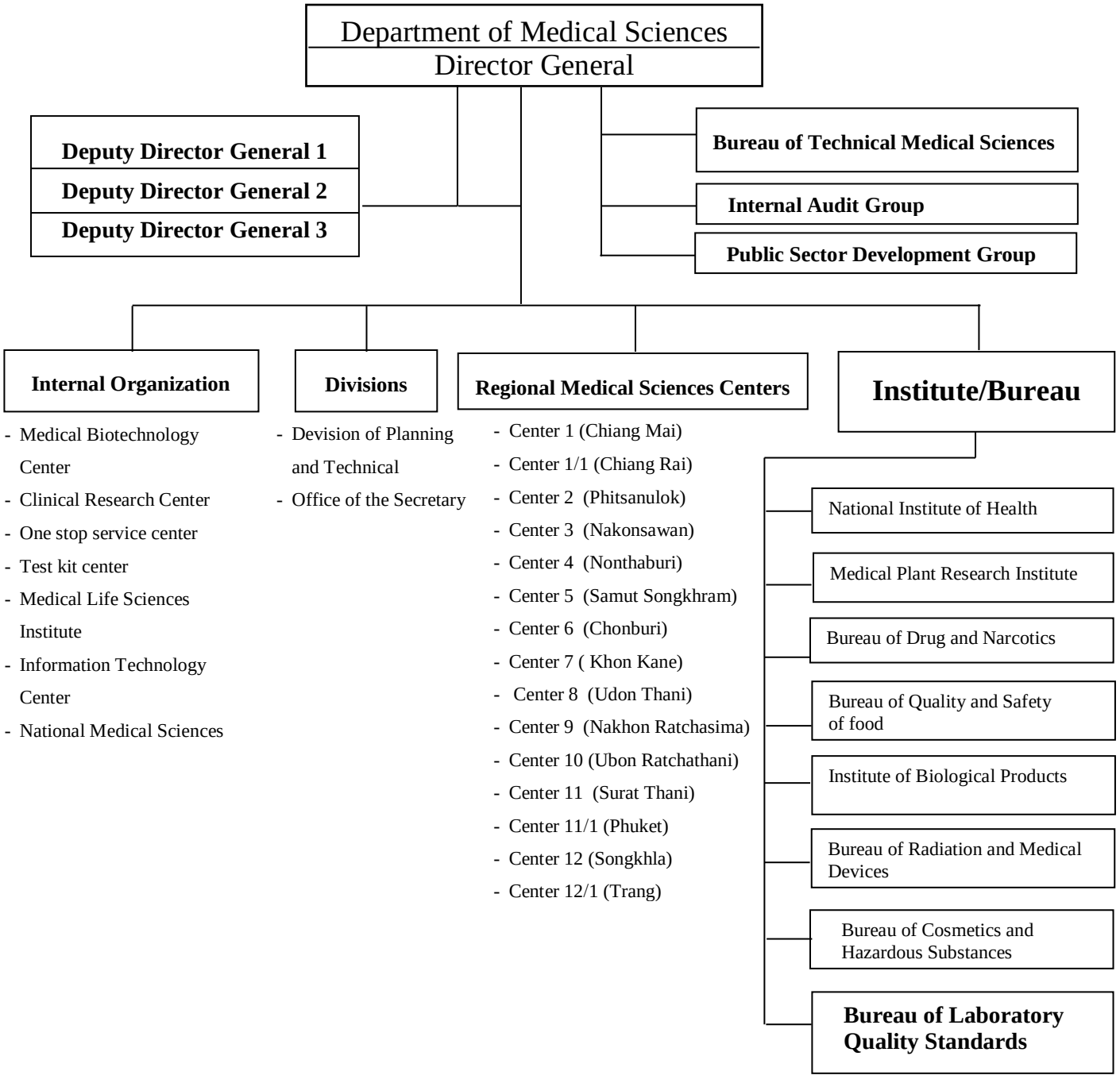
Related documents in Manual for Thailand GLP Compliance Programme

- WS 07 15 021/01: GLP application review
- F 07 15 025: Application for GLP compliance test facility
- F 07 15 026: Specific information for GLP compliance test facility
- F 07 15 027: Self-evaluation complying with OECD Principle of GLP
- F 07 15 051: Starting and Closing conference for GLP inspection
- F 07 15 057: Undertaking of Confidentiality
- F 07 15 078: Agenda and Notification of GLP Inspection
- F 07 15 082: Agenda and Notification of GLP Pre-Inspection
- F 07 15 083: Letter of statement of compliance

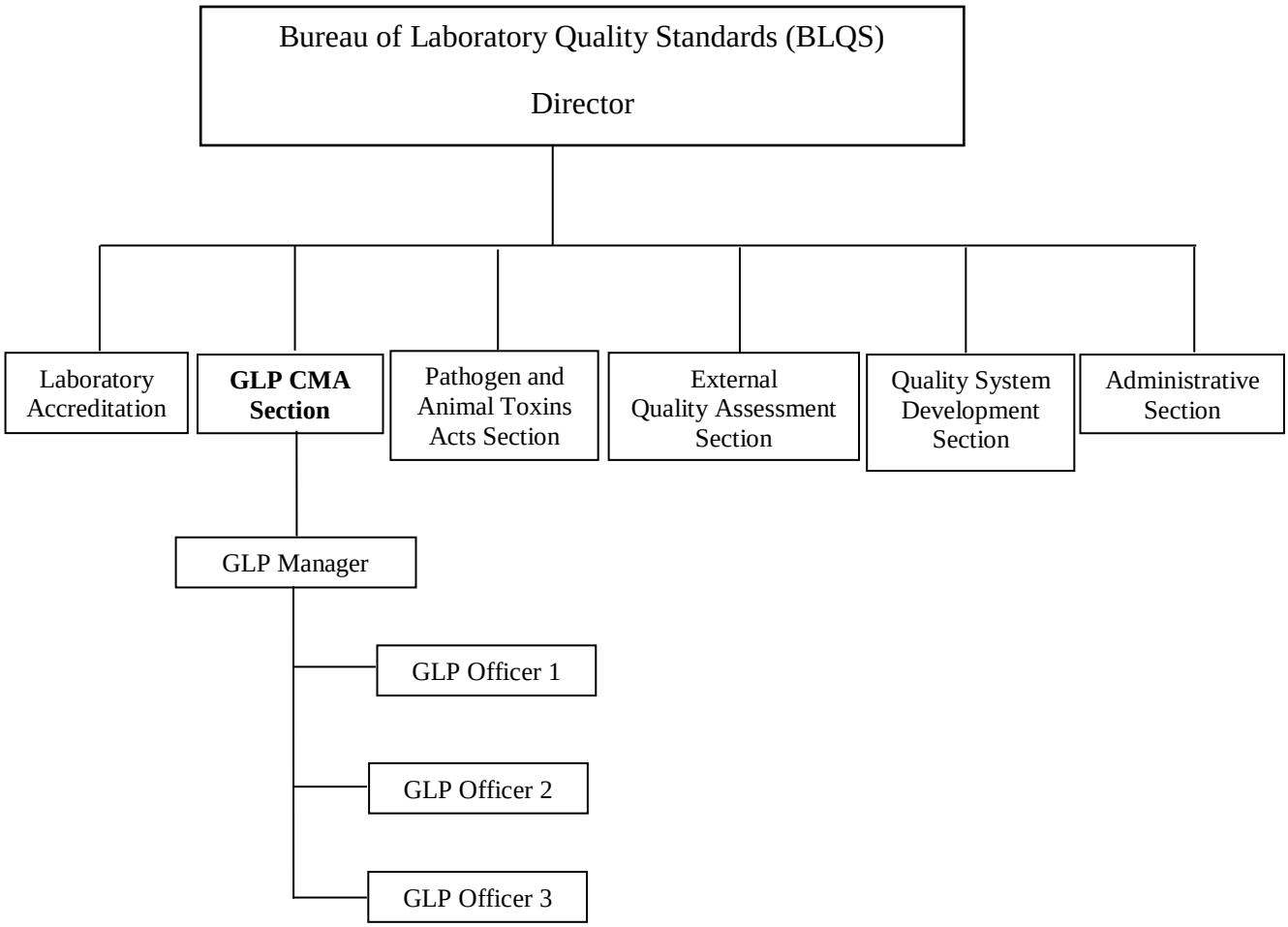
Annex 1: Administrative organizational structure of the Ministry of Public Health



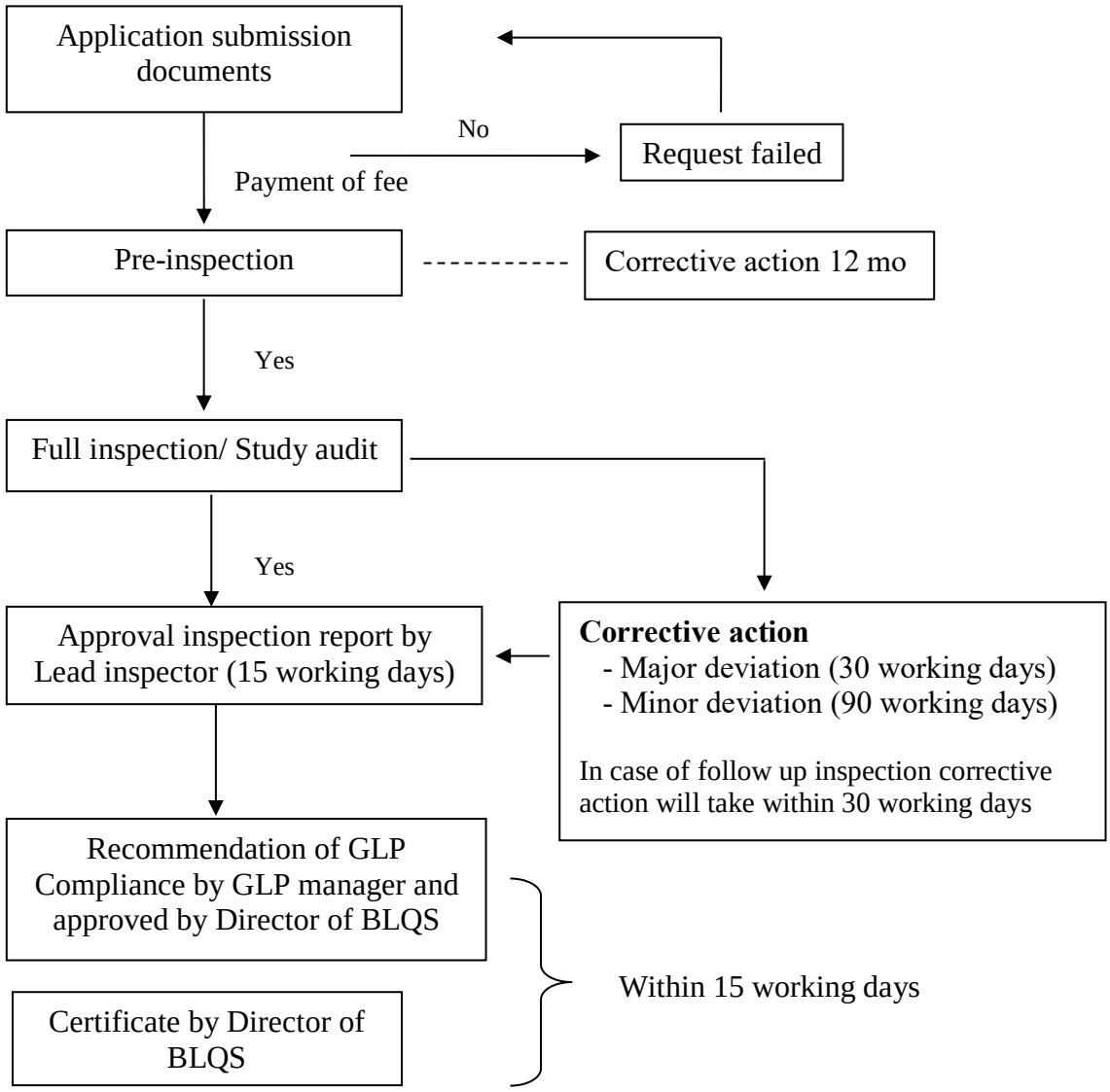
Annex 2: Organization chart of the Department of Medical Sciences



Annex 3: Organization chart of the Bureau of Laboratory Quality Standards



Annex 4: Registration Procedure Chart



Routine-inspection:

The 1st year after granting date for new applicant and then every two years subsequently.

Test facility shall apply for inspection at least 120 days before the expiry date. A full inspection will be carried out within 90 working days.

Extra Ordinary Inspection

Extra ordinary inspection shall be carried out in situation as listed below but not limited to:

- Follow up inspection to verify corrective action
- On the request of national or international authority
- Extension of new area of expertise
- Significant changes in the test facility (e.g changes of address, relocation, renovation etc)
- Others where necessary.

Annex 5: Standard Form of a GLP Compliance statement

กรมวิทยาศาสตร์การแพทย์
DEPARTMENT OF MEDICAL SCIENCES

Bureau of Laboratory Quality Standards (BLQS)

Certificate of Compliance to OECD Principles of GLP

GLP number
Test Facility
Address
Category of test item
Area of Expertise
Date of first Inspection
Date of last Inspection
Registration Number

The above mention test facility has been inspected and found to be operating in compliance to OECD Principles of Good Laboratory Practice and BLQS Compliance Programme. The inspection of compliance is conducted at regular basis.

(……)
Director
Bureau of Laboratory Quality Standards

Date of 1st Compliant
(first GLP compliant awarded)

Date of certificate issued**:**

Annex 6: Annual GLP Monitoring Report

Annual overview of test facilities inspected
Country:
Name of monitoring authority:
Date of submission:

Test facility/ Test site	Date of Inspection	Status	Nature of inspection	Area of expertise	remarks
Name and address Formal name (if applicable) and dates of name change					Explanation detail about particular inspection, date if modification of the area of expertise, date of removal from monitoring programme, other

Legends to the abbreviations used:

Test facility
Full name and address of the test facility

Date of inspection
Month and year of the inspection / study audit

Nature of inspection
- fac – facility inspection
- sa – study audit
- full – full inspection of facilities and studies (fac + sa)
- re-i-re – inspection as follow-up to a full inspection

Status
GLP compliance status of the test facility:
- ic – in compliance;
- nic – not in compliance;
- pen – pending;
- rfp – removed form programme: test facility is removed from GLP monitoring program

Area of expertise
The following codes should be used:
1. physical-chemical testing;
2. toxicity testing;
3. mutagenicity testing;
4. environmental toxicity studies on aquatic and terrestrial organisms;
5. studies on behaviour in water, soil and air; bioaccumulation;
6. residue studies;
7. studies on effects on mesosms and natural ecosystems;
8. analytical and clinical chemistry testing;
9. Other studies, specify.

Amendment Record

Manual for Thailand GLP Compliance Programme

Amendment		Discard			Revise or insert		
No.	**Date**	**Chapter**	**Page**	**Revision**	**Chapter**	**Page**	**Revision**
1	15 Nov 2009	Chapter 1-15	1-25	1st Ed., Rev 00	Review All Chapters and Modified annex 1, 2, 3, 4 and 6	1-23	2nd Ed., Rev 00
2	11 Nov 2011	10	15	2nd Ed., Rev 00	Modified Chapter 10 for better clarify in maintaining confidentiality and qualification of the Ad hoc committee	15	2nd Ed., Rev 01
3	17 Jul 2012	Policy for GLP Monitoring	2	2nd Ed., Rev 01	Change Name “Director General of the Department of Medical Sciences”	2	2nd Ed., Rev 02
4	6 Mar 2013	1	3,19, 20	2nd Ed., Rev 02	Modified responsibility of Laboratory Accreditation Section 2 for registration of test facility	3, 9 , 20	2nd Ed., Rev 03
5	1 Apr 2014	1, 3, 4 ,7, 10, 13. Annex 6	3, 7, 10, 14, 17, 23	2st Ed., Rev 03	Updated background according to the notification of the Food and Drug Administration dated 17 December 2015, review chapter 1, 3, 4, 7, 10, 13 for better clarify and Modified Annex 6 for detail in Annual GLP Monitoring Report	3, 7, 11, 12, 15, 17, 24	3rd Ed., Rev 00

Amendment		Discard			Revise or insert		
No.	**Date**	**Chapter**	**Page**	**Revision**	**Chapter**	**Page**	**Revision**
6	14 SEP 2017	-Policy for GLP Monitoring, - All chapter (Except13,14,15) - Annex 1,2,3,4,5,6	1,19, 20, 21	3rd Ed., Rev 00	Change Name - Director of Bureau of Laboratory Quality Standards - Deputy of Director Bureau of Laboratory Quality Standards - Head of Quality System Development Section - Review chapter 1,2,3,4,5,6,7,8,9,10,11,12,13,16 - Add list of documents - Annex 1,2,3 for change organization chart - Annex 4 For change registration procedure chart - Annex 5 For specify “certificate is valid for three (3) years from the date of this certificate issued” - Annex 6 for add the title of report	2,3,4, 5,6,7, 8,9,10 ,11,12 ,13,14 ,15,16 ,17,18 ,19,20 ,21,22 ,23,25 ,26,27	4rd Ed., Rev 00
7	30 MAR 2018	- Cover page - Policy for GLP Monitoring - Clause 1.1,4.5.8,6.5,9.5, 10.2,11.1,11.2,11.3,11.4, 12.2,12.3,13.1,14.2,16.2, -chapter 5,8 - Annex 3,4,5	2,3,7, 8,10, 11, 13-20, 25-27	4th Ed., Rev 00	- Change Name of revise in cover page - add details in Policy for GLP Monitoring - add details in clause 1.1, 4.5.8,6.5,9.5,10.2,11.1,11.2, 11.3,11.4,12.2,12.3,13.1,14.2,16.2 - add abbreviation - add details in confidential - remove BA/BE studies from the OECD GLP programme - Add details BE studies in compatible THAI-FDA - annex 3 modified organization chart - annex 4 modified registration procedure chart - add details in annex 5 Standard Form of a GLP Compliance statement	2,3,7, 8,10, 11, 13-20, 25-27	4th Ed., Rev 01

Amendment		Discard			Revise or insert		
No.	**Date**	**Chapter**	**Page**	**Revision**	**Chapter**	**Page**	**Revision**
8	8 JUN 2018	- Clause 6.5, 10.2, 11.3, 12.3 - Annex 4: Registration Procedure Chart	8.13, 15, 18,26	4th Ed., Rev 01	- Delete “working” - Add detail in clause 7 - Add Number 19 in clause 7.2 - Change telephone of BLQS CMA - Change time in clause Re-inspection - Add detail in clause 12.3 - Add clause 12.5 - Add detail clause 17 - Add WS 07 15 031 in related documents in Standard Operating Procedure - Change details in Annex 4	8,9,10 ,13,15 ,18,21 ,22,26	4th Ed., Rev 02
9	22 OCT 2018	- Chapter 1-17	1-32	4th Ed., Rev 02	- Revised all document	1-33	5th Ed., Rev 00

Controlled copy list

Name	Position	Organization
1. Dr. Patravee Soisangwan	Director, High level	Bureau of Laboratory Quality Standards Department of Medical Sciences
2. Dr. Archawin Rojanawiwat	Deputy Director and GLP manager	Bureau of Laboratory Quality Standards Department of Medical Sciences
3. Ms. Amornrat Tatsanakit	Head of Quality System Development Section	Quality System Development Section Bureau of Laboratory Quality Standards
4. Miss Thunyarat Sooksomboon	Medical Scientist, Practitioner level and GLP officer	GLP office Bureau of Laboratory Quality Standards