BUREAU OF LABORATORY QUALITY STANDARDS
DEPARTMENT OF MEDICAL SCIENCES

Quality Manual

Manual for Thailand GLP Compliance Programme

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Bureau of Laboratory Quality Standards, Department of Medical Sciences

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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 (BLQS CMA) 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, DOA 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.

(Mr. Surasak Muenphon)

Director

Bureau of Laboratory Quality Standards

1. Introduction

1.1 Background

The Bureau of Laboratory Quality Standards (BLQS) is government organization under the Department of Medical Sciences (DMSc), Ministry of Public Health according to the Reorganization of Ministry, Sub-Ministry, and Department ACT published in Thai Gazette No.119 Section 99ก dated October 2, 2002 (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.

The 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. The 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 the 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 organization structure of the Department of Medical Sciences according to the Ministerial Regulation on Structure of the Department of Medical Science, Ministry of Public Health published in Thai Gazette No.126 Section 98ก dated December 28, 2009 is presented in the organization 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 units 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 CMAs.

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 Principal 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

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

6. Requirements for Test Facility

6.1 The test facility must be legal identifiable and may comprise of 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 Non-clinical health and environmental safety study should be referred to OECD Test Guideline or other test guideline or other method.

6.4 The top management of the Test Facility or the authorized representative shall sign the application.

6.5 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 OECD GLP TF registration at all times. The authorized representative is expected to be present at staring and closing conference.

6.6 The application shall be submitted with the detail of the GLP management system and the implementation documents, which can fulfill the requirements of the BLQS CMA as mentioned in 10.2.

6.7 The test facilities shall comply with the registration procedure and shall pay fees as listed in Annex 6.

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

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

6.8.2 Prepare the evidences (e.g. SOPs, test items, references item, test system) during on-site inspection according to the request of the Inspectors, including hand-on analysis.

6.8.3 Provide the room for document reviews, meeting of Inspector team and other activities.

6.9 Test Facility Management is also reminded that legislation exists which controls the use of animals in experiments. Test Facilities should follow the up-to-date of Animal for Scientific Purpose Act.

7. Management System

The BLQS is appointed to be a National CMA by the National Standardization Council of which the Prime Minister is the chair of committee (The appointment letter no. MOI 0714/31429 dated 29th August 2018) for all studies area of expertise as mentioned in the scope of product. Thailand has become a full adherent to the OECD Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals and has accepted to join that part of the Chemicals Programme related to MAD, with all of the rights and obligations of member countries since September 7, 2020. (OECD letter no. ENV/EHS/BD/es/2020.113 dated 7th September 2020) 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 documented to ensure implementation of these policies and procedures in an independent and impartial manner and also to ensure the smooth operation of all compliance activities. The BLQS CMA management system has been established, documented, implemented and maintained to give confidence in its ability to operate the compliance process in an effective manner.

CMA manual, SOPs and Forms, inspection reports and other related documents develop by BLQS CMA are adopted from GLP principles.

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

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

Structure of Organisation

The Director General of Department of Medical Sciences delegates his authorization on National GLP compliance programme to the Director of BLQS as stated in the DMSc order no. 2703/2561 dated 6th September 2018.

The Director of BLQS is responsible for overseeing the operation of all national and international accreditation and national GLP compliance programme. The organisation charts of the DMSC and BLQS are shown in Annex 2 and Annex 3, respectively.

BLQS CMA is located on 5th floor (Room No. 510), Building 14, Department of Medical Sciences, 88/7 Tiwanon Road, Nonthaburi, 11000, Thailand. Tel. 029510000 ext. 99066, 99067.

8. Confidentiality

The BLQS CMA manual provides adequate arrangement consistent with the GLP principles 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.

- Ensure that, 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 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 in a Form *(F 07 15 023: Confidential, Financial and Conflict of Interest Statement)*.

9. Personnel and Training

9.1 The BLQS CMA 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 CMA can appoint a person to the position of BLQS GLP inspector or BLQS GLP lead inspector without 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 CMA 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 BLQS GLP lead inspector only after the appointment letter has been signed by the BLQS director which recommend by GLP manager.

9.7 The BLQS 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 BLQS GLP inspectors and BLQS 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 categories of inspection of the GLP Compliance Programme includes pre-inspection, full inspection (facility inspection and study audit), and extra ordinary inspections. The procedure for carrying out all category of inspection and study audit should be performed 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).

The BLQS CMA will conduct routine inspection (full inspection) in the first year after granting date and subsequently every two years. The inspection process is demonstrated in the flow chart as in Annex 4.

The BLQS CMA shall maintain a Master Register containing the name of test facility, the date of inspection, scope, the area of studies/expertise, compliance status and remarks. The Master Register is prepared by designated personnel, reviewed by GLP Manager and approved by Director of BLQS.

10.2 Test Facility Registration Process

The National GLP Compliance Programme is voluntary. The 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 the Test Facility claiming compliance with GLP.

The Test Facility shall submit documents as follows:

1. Application form no.5 (F 07 15 025): Applications form for GLP compliance test facility.
2. Application form no.6 (F 07 15 026): Detail of specific information for GLP compliance test facility.
3. Application 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. Nomination a GLP staff member as a coordinator to BLQS, DMSc.
10. Floor plan of the testing facilities.
11. Master schedules of all completed and on-going studies.
12. Full set of SOPs (include list of SOPs)
13. List of equipment.
14. Quality Manual or other names.
15. Study plan and Final report.
16. List of personnel and Curriculum vitae.
17. OECD Test Guidelines or other test guideline or method.

Test Facility shall provide original documents no. 1 – 3, two hard copies and two removable drives containing documents no. 1 - 17. All documents must be properly sorted and labelled according to the *List of documents submit to BLQS for inspection (F 07 15 198)*. The documents 1 – 3 and *List of documents submit to BLQS for inspection (F 07 15 198)* can be downloaded from http://blqs.dmsc.moph.go.th. The controlled release of all documents is the responsibility of the Test Facility.

All documents will be completely checked by GLP officer using *WS 07 15 021/01: GLP application review* within 10 working days. GLP officer will inform the Test Facility if the documents are not completed and the Test Facility will have to submit additional documents as requested within 20 working days. The BLQS CMA will terminate the application of the Test Facility if the request cannot be done. For the first entry to the programme, the Test Facility shall have at least **one completed study and one on-going study*** that has been conducted in compliance with the OECD GLP principles. GLP officer will assign test facility code number as described in *SOP 07 15 030: Assignment test facility registration and code number*. GLP officer will then request the Test Facility to pay the fees. The registration fees are categorised as mentioned in Annex 6.

After payment, the BLQS CMA will prepare an invitation letter to a lead inspector, inspector (s), and expert (s) where necessary, to conduct inspection. If the invitation is accepted, he/she will be requested to sign on *Consent of acceptance as inspectors Form (F 07 15 022)* and *Confidential, Financial and Conflict of Interest Statement Form (F 07 15 023)* will be delivered to the inspector team. Meanwhile, The BLQS CMA will subsequently request acceptance of the

proposed inspector team from the test facility via email or letter. If there is any objection, an official letter from the test facility should be summited to BLQS CMA within 15 working days. A new inspector team will be assigned only when reasons are accepted by BLQS's Director.

The BLQS CMA will appoint the inspector team according to *SOP 07 15 024: Appointment of inspector.* GLP officer will discuss with the GLP manager on an inspection schedule. The final agenda *(F 07 15 082: Agenda and Notification of GLP pre-inspection/F 07 15 078: Agenda and Notification of GLP inspection*) will be delivered to the test facility at least 10 working days prior to the inspection date.

11. Category of Inspection

11.1 Pre-inspection

Pre-inspection is carried out when the Test Facility firstly registers to the programme. Pre-inspection will be conducted within 90 working days upon receiving completed application document including payment. The pre-inspection schedule *(F 07 15 082: Agenda and Notification of GLP pre-inspection)* will be officially informed to the test facility for at least 10 working days before inspection date. A pre-inspection is normally carried out within one day to assess the establishment of the OECD Principles of Good Laboratory Practice as well as policy, requirements and conditions of BLQS CMA in the test facility. The detail of Pre-inspection process is described in *SOP 07 15 027: Pre-inspection*. Prior to inspection date, the inspector team should have a meeting to review documents and plan for inspection.

At the starting conference, it is necessary that Test Facility Management (TFM) or Authorized Representative, Study Director, Archivist and QA staffs should be present during the pre-inspection, especially at starting and closing conference. All participants have to sign on the form: *F 07 15 051: Starting and closing conference for GLP inspection*. Lead inspector should describe the purpose and scope of the visit. The Lead inspector should also inform that the normal work could be slightly disturbed and additional documents and records may be requested during pre-inspection. TFM should be requested to make a presentation concerning the organisation and the activities of the test facility.

The inspector team should at least observe the environmental conditions, the identification and storage of apparatus, test systems, test and reference items and archives in order to familiarize facility management. The result of pre-inspection will be verbally given at the closing conference. The BLQS CMA shall send the official pre-inspection report (*WS 07 15 027/01: GLP Pre-Inspection Report)* to test facility within 15 working days. Test Facility should take appropriate actions and should summit to BLQS CMA within 6 months after pre-inspection date. If not, the BLQS CMA will consider to remove from the programme. The Test Facility can, however, reapply to the programme as a new registrant.

11.2 Full Inspection

The full inspection is involved for both facility inspection and study audit. The inspection should be conducted for at least 2 – 5 working days depending on number of studies conducted by test facility. The duration of the inspection can be extended during the inspection with one or more days depending upon the size of the Test Facility and the numbers of studies to be audited or unforeseen situations. All details of conducting test facility inspection and study audit were mentioned in *SOP 07 15 031: The conduct of test facility inspections and study audit.*

The inspector team consists of a lead inspector and inspector(s) or expert(s) (where necessary). The inspection agenda (*F 07 15 078: Agenda and Notification of GLP inspection*) will be officially informed to the test facility for at least 10 working days before inspection date.

Prior to inspection date, the inspector team should have a meeting to select the studies for auditing. The numbers of the completed studies should be randomly selected depending on (1) If the test facility has less than eight completed studies, all studies will be audited (2) If the test facility has more than eight completed studies, at least eight studies will be randomly selected. The Test Facility should have at least one ongoing study to be audited for performance during full inspection.

At the starting conference, it is necessary that TFM or Authorized Representative, Study Director, Archivist and QA staffs should be present during the full inspection, especially at starting and closing conference. All participants have to sign on the form: *F 07 15 051: Starting and closing conference for GLP inspection*. Lead inspector should describe the purpose, confirm the scope and area of expertise for inspection, and identify the test facilities areas, study selected for audit, documents and personnel involve in inspection process. The Lead inspector should also inform that the normal work could be slightly disturbed and additional documents and records may be requested during full inspection. TFM should be requested to make a presentation concerning the organisation and the activities of the test facility. A meeting room for reviewing documents and other activities should be provided throughout the inspection. TFM should assign appropriate personnel to accompany the inspectors.

The facilities inspection should be conducted on the first day. During the full inspection, inspectors may interview TFM, QA, Study Director, Study Personnel and Archivist of the test facility. The inspection team will not be concerned with the scientific design of the study or the interpretation of the findings of the studies.

Any deviations and observations are found; each inspector should record in *F 07 15 034: Record of inspection*. The inspector team should discuss, summarize their findings and prepare a draft inspection report in *F 07 15 036: On-site Report of Inspection/Study Audit*. 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 clause 12 Approval of inspection)

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

The inspector should discuss their findings with representative of the test facility at a closing conference. If there is no objection on the findings, The test facility will be informed of the possible outcomes (a) In Compliance or (b) Not In Compliance. The draft on-site report (*F 07 15 036: On-site Report of Inspection/Study Audit*) will then be finalized and signed. The test facility shall describe actions taken with evidences in regard to all deviations and observations using the signed on-site report form within the timeframe for deviation according to clause 12.

The inspection team will prepare a final report on inspection using *WS 07 15 023/01: Report on inspection of test facility* as described in *SOP 07 15 023*: *Preparation of inspection report* based on OECD document *No.9, Guidance for the Preparation of GLP Inspection Report, (1995)*. The final report should be completely done with sign and date by the inspector team within 15 working days after the corrective actions are satisfied.

Note:

1. Routine inspection is the full inspection of certified test facility to ensure and monitor its GLP compliance for certificate renewal. It will be conducted at the first year within validity of each TF and inspected every two years onward approximately on

the last inspection date. Prior to the valid date, test facility shall apply for routine inspection at least 120 working days. The inspection will subsequently be conducted within 60 working days before the valid date.

2. The certified test facility shall have at least one new completed study in every area of expertise for each year.
3. In case of serious or major deviations from the GLP Principles are observed, the lead inspector can decide to stop the inspection earlier than planned and should report back to the CMA within 5 working days.

11.3 Extra Ordinary Inspection

The following are other circumstances that may require facility inspections and/or study audits as listed below but not limited to:

- **An extension of area of expertise:** Where an area of expertise is extended before the next round of routine inspection, the test facility may request to apply for full inspection.
- **A follow up inspection:** Where corrective actions taken by the test facility are not completely satisfied, the inspector may propose to on-site verification of those corrective actions.
- **A significant change:** Where relocation, major renovation, TF name changes or new TFM occurs in the facility, the test facility shall immediately address to BLQS CMA. The Director of BLQS CMA will consider whether the full inspection is required.
- **A request from Regulatory Authority and/or Compliance Monitoring Authority:** Specific Study Audits may be requested by other CMAs or local Regulatory Authorities. Such requests may sometimes involve Test Facility Inspections.
- **Others** where necessary.

12. Approval of inspection

Findings that are not in compliance with the OECD Principles of GLP, BLQS GLP CP and Test Facility's procedure, the inspector team should classify as deviation or observation.

Deviation:

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.

When deviation is observed appropriate corrective action shall be taken by the test facility within 45 working days from the date signed on the on-site report. If corrective action is not submitted within the timeframe, the GLP manager will make recommendation to Director of BLQS for consideration to remove the test facility from the programme.

If corrective action is submitted within the timeframe, the inspector team will review the corrective actions within 10 working days. When corrective actions of all deviations are satisfied, the inspector team will make the inspection report *(WS 07 15 023/01: Report on inspection of test facility)* and submit it, including the on-site report (*F 07 15 036: On-site Report of Inspection/Study Audit*), to the BLQS CMA within 15 working days.

The GLP manager will check all documents, prepare the recommendation *(WS 07 15 031: Recommendation for GLP registration by BLQS)* and submit to the Director of BLQS for final decision within 10 working days. For test facility found to be in compliance, the Director of BLQS will issue Certificate of Compliance to OECD GLP (Annex 5) and a letter of Statement of Compliance *(F 07 15 083: Letter of Statement of Compliance).*

Note: If the inspector team requests more evidences of corrective actions taken, the test facility should submit within 10 working days. Follow up inspection will be considered where corrective actions taken remain dissatisfied. If the follow up inspection is still not satisfied, then the GLP manager will be recommended to remove the test facility from the programme.

Where serious deviations are found, the action taken by BLQS CMA will depend upon the particular circumstances of each case and the legal or administrative provisions under which Thailand GLP Compliance Programme has been established. Actions which may be taken include, but are not limited to, the following:

- 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 Thailand 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.

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 no effect(s) on validity and integrity of data.

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

13. Status of GLP Compliance

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

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

(b) Not In Compliance with GLP (nic): 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.

(c) Pending (pen): The test facility is under an appeal process.

14. Removal of test facility

The BLQS CMA may also remove test facilities from the National GLP Compliance Programme in the right of:

a) Failure to comply with National GLP Compliance Programme requirements as stated in this manual;

b) Failure to provide cooperation or facilities for BLQS CMA, its inspectors and/or its authorized representatives to perform 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 facility 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.

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 CMA will consider whether it is necessary to conduct pre-inspection or a full inspection can be conducted directly.

15. Withdrawal of the registration

The test facility will officially inform withdrawal the registration to BLQS CMA under the following circumstances.

15.1 The test facility is declared bankrupt from courts.

15.2 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.

15.3 Test facility discontinues its functions.

The withdrawal procedure is followed *SOP 07 15 025: Withdrawal of Registration*

16. Appeals

The test facility has the right to file an appeal in writing to the Director General of DMSc under the categories below;

16.1 Registration decision: 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 received from the GLP Inspector.

16.2 Removal of test facility: as described in clause 14.

To file the appeal, Test Facility Management should submit to the Director General of DMSc, who is the chairman of the Appeal Committee within 15 days after the notice is officially informed. The Director General will appoint at least three independent persons from the Appeal Committee to review and make the final decision on behalf of the Appeal Committee. External experts may be co-operated, when required. The decision of the Appeal Committee shall be made within 90 days. During the appeal process, the status of Test Facility is classified as

pending. If the consideration cannot be completed within such period of time due to a cause of necessity, a written notice shall be given to the Test Facility. In this regard, the period of time for the consideration of the appeal may be extended for not more than 60 days. The final status of the Test Facility is defined by the Appeal Committee. The Appeal Committee' s decision shall be final.

The member of the Appeal Committee comprises at least representatives from Food and Drug Administration, Ministry of Public Health, Department of Agriculture, Ministry of Agriculture and Cooperatives, The Thai Industrial Standards Institute (TISI), Ministry of Industry and relevant Professional Association. They should have knowledge 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)*.

17. 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 CMA *(WS 07 15 026/01: Complaint of Registration)*. The discontent or accusation can be aimed at the BLQS staffs, inspectors or experts acting on behalf of the authority and which is relevant to performance or behavior of BLQS CMA service. The complaint is managed by GLP manager within 60 days. In case of the complicate one, more than 60 days may be needed. The complaints will be recorded on Complaint Log Form *(WS 07 15 026/02: Complaint Log Form)*. The result of the complaint(s) will be reported to the complainant. The complaint procedure is followed *SOP 07 15 026: Complaint of Registration*.

18. Right and Duties

18.1 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.

18.2 The BLQS CMA archives the original of the onsite and final inspection reports. A copy of on-site and final inspection reports is sent to the test facility.

18.3 Foreign CMA could request the final report of TF of concerned if any doubt or more explanation required for register in their country.

18.4 Provide special Test Facility Inspections/Study Audits at the request of a Regulatory Authority.

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

18.6 BLQS CMA should ensure that Inspectors are adequately qualified and trained and have their powers for entry into test facilities and access to data held by test facilities.

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

18.8 Complaints or appeals can be made to GLP officer.

18.9 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.

18.10 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 CMA within 15 working days.

18.11 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 CMA regardless of the outcome of these activities. Any failure may result in the withdrawal of the registration.

18.12 The test facility must not make any statement about its GLP - compliant status to mislead the public as well as to bring BLQS CMA into disrepute.

18.13 The test facility must not use GLP - compliant status to imply approval of any products or substances by BLQS CMA.

18.14 The test facility must immediately stop making reference to terms "GLP – compliant facility" or "GLP - registered facility" on all advertising materials which contains the terms or refers to them when the test facility is withdrawn from National GLP Compliance Programme.

19. Communication and information

BLQS CMA cooperates closely with relevant receiving authorities such as DOA (pesticides) and FDA (pharmaceuticals) and informs them on GLP – compliant and current status of test facilities in Thailand and MAD countries.

BLQS CMA may provide information to facilitate the communication between sponsors, test facilities, national or foreign Regulatory and foreign Monitoring Authorities, as follows;

- The conclusions of GLP inspection and a "Statement of GLP compliance": This information will be made available on request to the national or foreign Regulatory Authorities concerned.

- The list of GLP - compliant test facilities: It is available on website http://blqs.dmsc.moph.go.th, https://blqs.dmsc.moph.go.th/page-view/129

- Annual overview of GLP monitoring report submitted to the OECD GLP Working Party Secretariat (Annex 7): This information can only be accessed by authorized CMAs and RAs from OECD GLP Working Party website.

20. Archives

The authorized personnel can access to the documents maintained in BLQS CMA locked archive. There are two types of documents that shall be archived:

20.1 Documents related to BLQS GLP Compliance Monitoring Programme.

- The manual of BLQS GLP Compliance Monitoring Programme.

- Records of qualification and experience, training and job descriptions of inspectors and CMA personnel.

- Other CMA documents, if any

- All procedures, worksheets and forms.

The BLQS CMA will retain the above records at a designated area for at least 5 years.

20.2 Documents related to GLP inspection of the test facilities.

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

All documents (hard copy and CD/ external drive) related to GLP inspection of test facilities are stored and retained in the archive room for at least 10 years except for inspection reports and /or summary reports will be perpetually retained. One original hard copy of applicant will be returned after the certificate is issued and the other one will be retained at BLQS CMA.

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

21. References

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

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.

20. Guidance Document for Receiving Authorities on the Review of the GLP Status of Non-Clinical Safety Studies, 2019.

21. OECD Position Paper Regarding Possible Influence of Sponsors on Conclusions of GLP Studies, 2020.

22. Advisory Document of the Working Party on Good Laboratory Practice on GLP Data Integrity, 2021.

23. Advisory Document of the Working Party on Good Laboratory Practice on Quality Assurance and GLP, 2022.

24. Position Paper on Quality Improvement Tools and GLP, 2022.

25. OECD Position Paper on Good Laboratory Practice and IT Security, 2024.

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.
- WS 07 15 022/02: Monitoring Trainee Inspector's Performance.
- F 07 15 023: Confidential, Financial and Conflict of Interest Statement.
- F 07 15 079: Curriculum vitae & Training record.

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 15 027/01: GLP Pre-Inspection Report.
- WS 07 15 027/02: GLP Pre-Inspection Checklist.
- F 07 15 034: Record of inspection.
- F 07 15 051: Starting and Closing conference for GLP inspection.
- F 07 15 082: Agenda and Notification of GLP Pre-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 15 023/01: 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.
- F 07 15 051: Starting and Closing conference for GLP inspection.
- F 07 15 078: Agenda and Notification of GLP Inspection.
- F 07 15 083: Letter of Statement of Compliance.

SOP 07 15 044: SOP for Archive.

- F 07 15 056: Entrance and Exit of Archive Room.

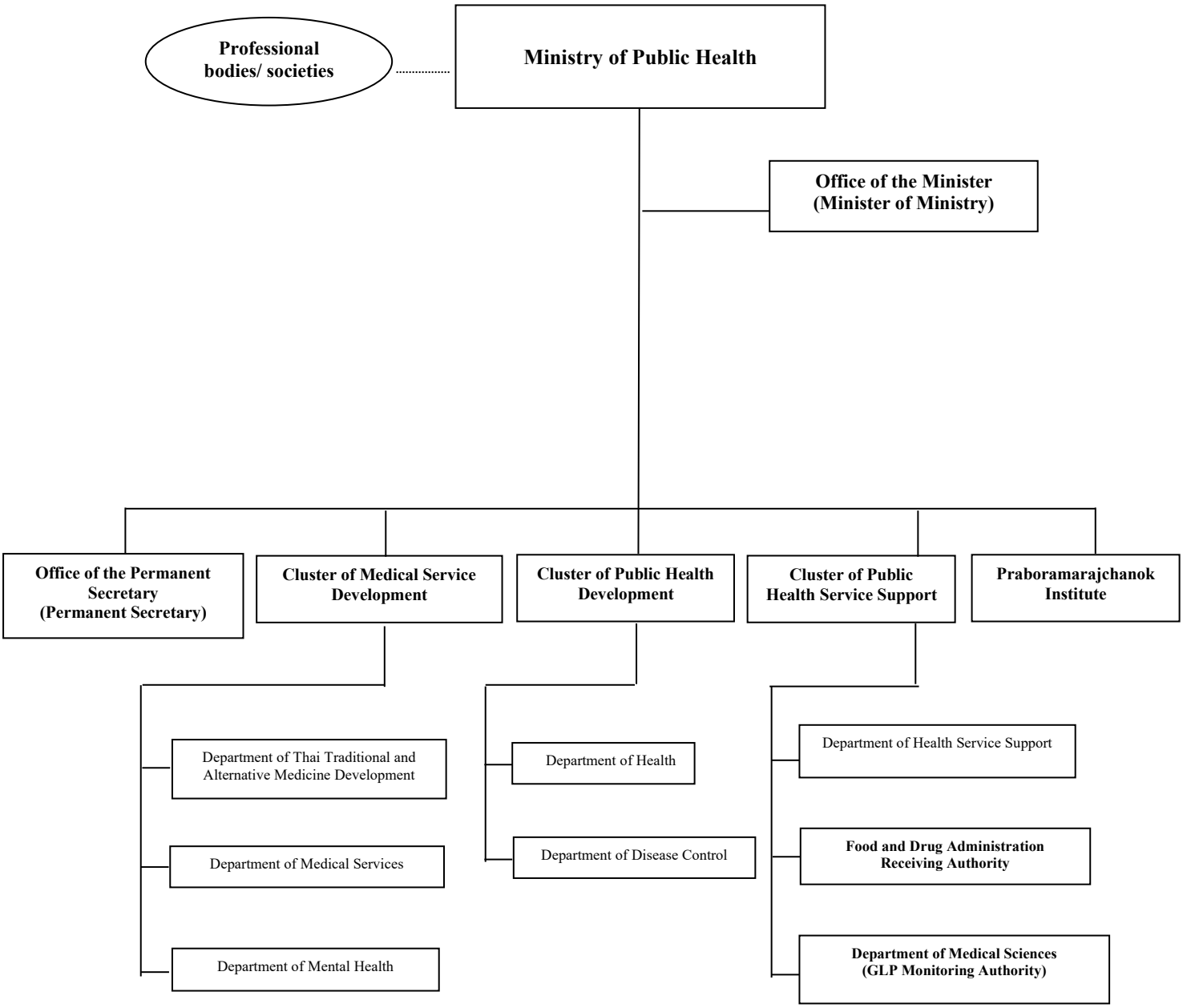
SOP 07 15 046: SOP for Remote GLP Inspections.

- WS 07 15 023/01: Report on inspection of test facility.
- F 07 15 034: Record of inspection.
- F 07 15 036: On-site report of inspection/study audit.
- F 07 15 051: Starting and Closing conference for GLP inspection.
- F 07 15 078: Agenda and Notification of GLP Inspection.

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 15 057: Undertaking of Confidentiality.
- F 07 15 198: List of documents submit to BLQS for inspection

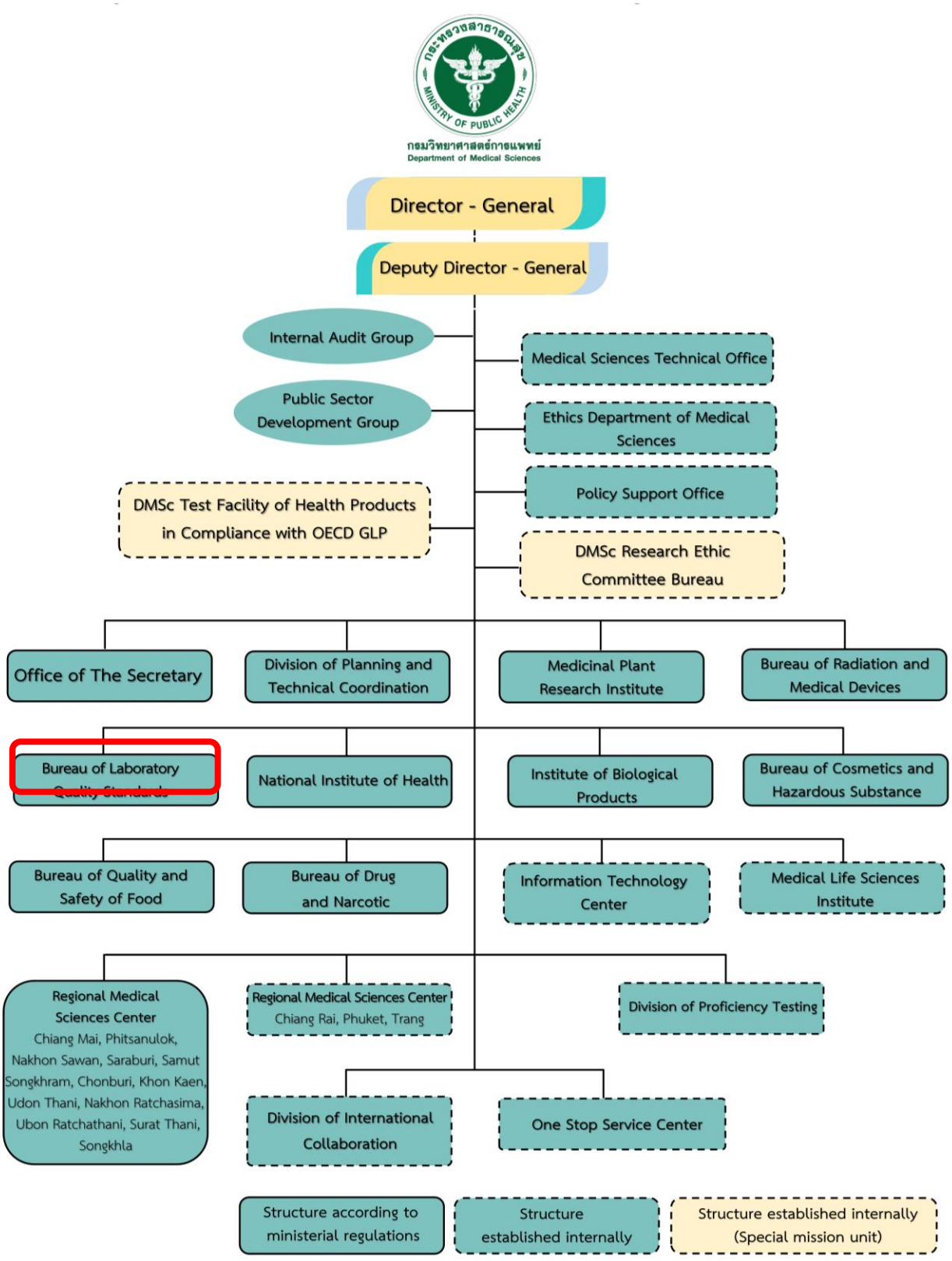
Annex 1: Organization structure of the Ministry of Public Health



Cited: https://opdc.moph.go.th/structure_moph.php

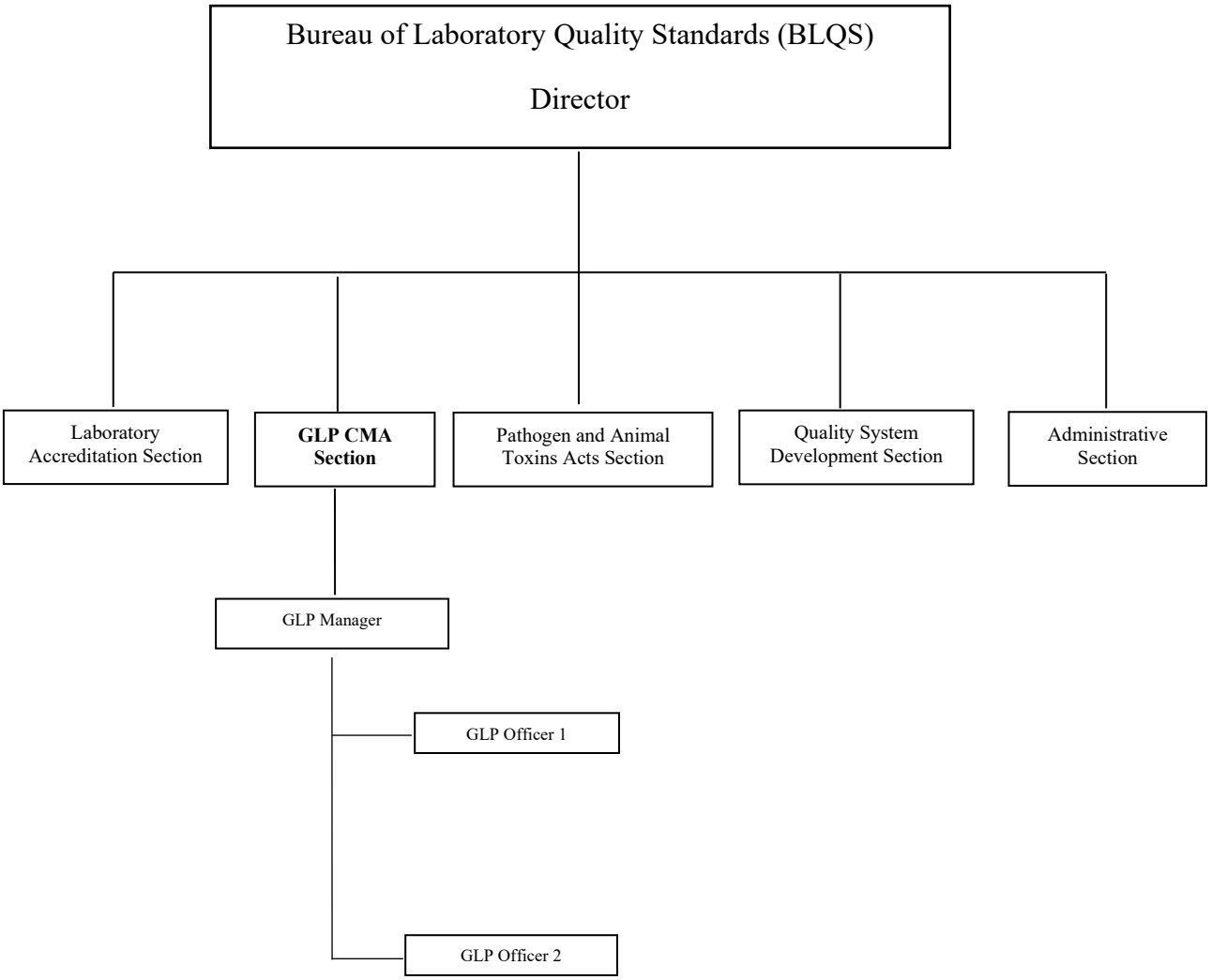
(Unofficial translate)

Annex 2: Organization chart of the Department of Medical Sciences

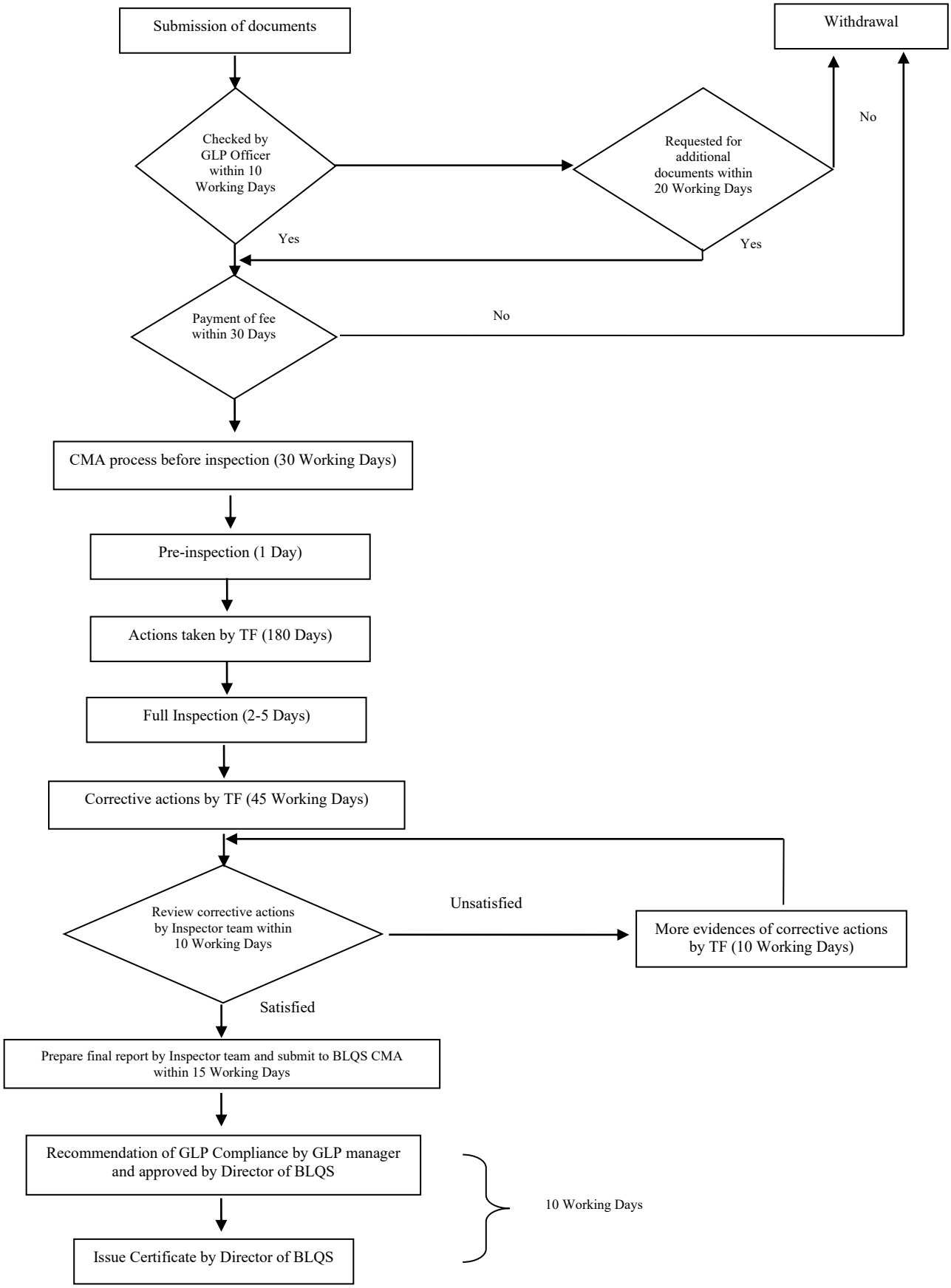


Cited: https://www3.dmsc.moph.go.th/en/page-view/72

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



Annex 4: Inspection Process



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 name:

Address:

Category of test item contained in products:

Area of Expertise:

Date of 1st Compliance: (Day/Month/Year)

Date of last Inspection: (Day/Month/Year)

This is to certify that (Test Facility name) is a GLP certified test facility in compliance with OECD Principles of Good Laboratory Practice and BLQS Compliance Programme.

(……..……)

Director

Bureau of Laboratory Quality Standards

Validity: (Day/Month/Year) - (Day/Month/Year)

Issue date: (Day/Month/Year)

Annex 6: Fees

Test Facility inspection fees are as follows:

Documentation Review:	
- Full inspection (first application)	Baht 10,000/ inspection
- Routine inspection	Baht 10,000/ inspection
- Extending scope/area of expertise	Baht 10,000/ inspection
Certificate of Compliance to OECD GLP	Baht 25,000/ inspection
Inspection Fee:	
- Lead inspector	Baht 12,000/ inspection
- Inspector	Baht 9,000/ inspection
- Expert	Baht 6,000/ inspection
Annual fee	Baht 2,000/ year
Replacement of Certificate	Baht 2,000/ request

Note: Travelling and accommodation expenses of the inspector team will be covered by the test facility.

Annex 7: Annual overview of GLP Monitoring Report

Name of test facility	**Former name of test facility at the time of inspection**	**Address of test facility at the time of inspection**	**Country of test facility at the time of inspection of the test facility**	**Name of non-adherent country at the time of inspection, if applicable**	**Name of inspecting CMA**	**Inspecting country**	**Product types**	**Date of inspection**	**Status**	**Nature of inspection**	**Area of expertise**	**Remarks**
Name of the test facility	Former name(s) if applicable	Address of the test facility	The country where the test facility is located	The country if the test facility locates in a non-MAD adherent country	Specify the name of the inspecting CMA	Select the country	Specify the name of products	Year and month of the inspection / study audit				Explanation about pending status, detail about particular inspection, date of removal from monitoring programme, new name in the case of rfp due to the name change, others

Legends to the abbreviations used:

Status

GLP compliance status of the test facility:

- ic – in compliance;
- nic – not in compliance;
- pen – pending, explanation in Remarks field;
- rfp – removed from programme: test facility is removed from GLP monitoring program

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

Area of expertise

The following codes should be used:

1. Physical-chemical testing (Section 1 – Physical Chemical Properties);
2. Toxicity testing (testing other than mutagenicity testing in Section 4 – Health Effects);
3. Mutagenicity testing (testing on mutagenicity in Section 4 – Health Effects);
4. Environmental toxicity studies on aquatic and terrestrial organisms (Section 2 – Effects on Biotic Systems);
5. Studies on behaviour in water, soil and air; bioaccumulation (Section 3 – Degradation and Accumulation);
6. Residue studies (Section 5 – Pesticides Residue Chemistry);
7. Studies on effects on mesosms and natural ecosystems (Section 2 – Effects on Biotic Systems);
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., Rev00	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	2nd 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
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	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

Amendment		Discard			Revise or insert		
No.	**Date**	**Chapter**	**Page**	**Revision**	**Chapter**	**Page**	**Revision**
					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		
7	30 MAR 2018	- Cover page - Policy for GLP Monitoring - Clause1.1,4.5.8,6.5,9.5, 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
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	8, 9, 10, 13, 15, 18, 21, 22, 26	4thEd., Rev 02

Amendment		Discard			Revise or insert		
No.	**Date**	**Chapter**	**Page**	**Revision**	**Chapter**	**Page**	**Revision**
					related documents in Standard Operating Procedure - Change details in Annex 4		
9	22 OCT 2018	- Chapter 1-17	1-32	4th Ed., Rev 02	- Revised all document	1-33	5th Ed., Rev 00
10	11 Aug 2021	- Cover page - Clause 10.2, 11.1, 11.2, 11.4, 17 - Related documents in Standard Operating Procedure - Annex 4: Registration Procedure Chart	12, 14, 16, 22, 23, 27, 33	5th Ed., Rev 00	- Change Name of review and revise in cover page - Delete "Copy of house registration and identification of the applicant" and edit detail in supporting document in cluse 10.2 - Add worksheets in clause 11.1 - Add detail for routine inspection in clause 11.2 - Change detail of fees in clause 11.4 - Add OECD series of document no.20 and 21 in clause 17 - Add worksheets, forms and new SOP in related documents in Standard Operating Procedure - Add detail for routine inspection in Annex 4 - Change controlled copy list	12, 14, 16, 22, 23, 27, 33	5th Ed., Rev 01
11	16 Jun 2022	- Clause 11.2, 12.2, 17 - Related documents in Standard Operating Procedure - Annex 5: Standard Form of a GLP Compliance statement	14, 17, 22, 23, 28	5th Ed., Rev 01	- Updated the format of QM - Add detail in paragraph 1 and 4 - Add note in clause 12.2 - Add OECD series of document no.22 in clause 17 - Add worksheets, forms and new SOP in related documents in Standard Operating Procedure - Add "contained in products" in "Category of test item"	15, 18, 23, 24, 30	5th Ed., Rev 02

Amendment		Discard			Revise or insert		
No.	**Date**	**Chapter**	**Page**	**Revision**	**Chapter**	**Page**	**Revision**
12	19 Sep 2024	- Clause 10.2, 11.2, 17 - Related documents in Manual for Thailand GLP Compliance Programme - Annex 2: Organization chart of the Department of Medical Sciences - Annex 3: Organization chart of the Bureau of Laboratory Quality Standards - Annex 5: Standard Form of a GLP Compliance statement - Annex 6: Annual GLP Monitoring Report	12, 15, 23, 25, 27, 28, 31	5th Ed., Rev 02	- Change revised name - Add "Application" in clause 10.2 - Add OECD Test Guidelines or other test guideline or method and detail in clause 10.2 - Delete "corrective actions" and add "response" in clause 11.1 - Delete "deviations observed" and add "result of the finding and send the response to BLQS within 6 months till 12 months" in clause 11.1 - Delete "a written report" and add "(*F 07 15 036: On-site Report of Inspection/Study Audit*) in clause 11.2 - Move position of "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 were mentioned in *SOP 07 15 031: The conduct of test facility inspections and study audit.*" in clause 11.2 to upper at 2nd paragraph on page 16 and add "by using the on-site report". - Add "The inspection team will prepare a report	12, 13, 14, 16, 23, 25, 27, 28, 31	5th Ed., Rev 03

Amendment		Discard			Revise or insert		
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					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 within 15 working days after the corrective actions accepted by the lead inspector and team." in clause 11.2 - Delete "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" in clause 11.2 - Add "(*WS 07 15 023/01: Report on inspection of test facility*)" in clause 11.2 - Change details in Note of clause 11.2 - Add OECD series of document no.23 and 24 in clause 17 - Add new form in Related documents in Manual for Thailand GLP Compliance Programme - Updated Administrative organizational structure of the Ministry of Public Health in Annex 1 - Updated the Organization chart of the Department of		

Amendment		Discard			Revise or insert		
No.	**Date**	**Chapter**	**Page**	**Revision**	**Chapter**	**Page**	**Revision**
					Medical Sciences in Annex 2 - Delete the External Quality Assessment Section in Annex 3 - Change wording of "Compliant" into "Compliance" in Annex 5 - Name change and updated the format in Annex 6: Annual overview of GLP Monitoring Report		
13		- Cover page - Chapter 1 - 17	1 - 31	5th Ed., Rev 03	- Revised all document	1 - 32	6th Ed., Rev 00