A request and specific information for laboratory accreditation

For official only

CAB No. ……..……...

Place.....

Date.....

Part 1 General Information

1. Applicant Information

Name of applicant …….....….…….

( ) Top management ( ) Authorized representative

Identification Number ……..….. Age……..… yrs Nationality……...……..…

Issued at……..…… Issued Date ……..…….. Expired date….....

Address……

……..……

Telephone Number: ……..… Mobile Number: ……..…….. E-mail address: ……..

Note: Power of attorney:

For government organization/ state enterprises, one of the following is followed:

1. Letter of Power of Attorney specifies the individual authorized to perform and the matter delegated clearly, signed by grantor of authorization, authorized representative and two witnesses.
2. Official Letter specifies the individual authorized to act and the matter delegated clearly, signed by the Top management.

For private organizations, Letter of Power of Attorney affixing a 30 Baht of revenue stamp is required.

2. Laboratory information

2.1 Legal status:

○ Government organization ○ State enterprises ○ Public limited company ○ Private limited company

○ Other, please specify.....

Date of established of laboratory: ……**Registration number:** …….

(company/ trade registration or etc. to be attached)

Note: For government organization/ state enterprises, please attach the information of establishment, including government act of establishment, organization, royal decree on establishment of departments, or any other documents demonstrating legal entity.

License to operate a sanatorium (For medical laboratory)

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License to management of a sanatorium (For medical laboratory)

……

2.2 Name of laboratory

……

Address of laboratory

……

2.3 Nomination a senior staff member as a representative in all dealings with BLQS, DMSc

Name……..…… Position……..……..…….....

Telephone……..... Fax …… Mobile……..……

E-mail address ..... Line ID…….....

2.4 Name of key person

Name of Top management/Laboratory management……..…… Position.……

Name of Quality manager……..… Position.……...

Name of Technical manager…….. Position.……...

Name of Laboratory director (For medical laboratory) …… Position.……

Name of Laboratory safety officer (For medical laboratory) ……...…….

The laboratory has other standards such as ISO 9001, ISO 14000, ISO 14001, ISO 22000, etc.

Please specify name of top management of each standard …… Position.……

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Please consideration of conformity with the standard accredited from BLQS

☐ Conformity ☐ Nonconformity

How could you organize if it does not conform? ……..……..

……

2.5 Purpose of request

○ New accreditation, please specify ( ) Pre-assessment ( ) On-site assessment

○ Re-assessment ○ Extended scope ○ Surveillance

Note: Laboratory apply for new accreditation can choose the pre- assessment before the on-site assessment as follows:

- Pre-assessment: 1-2 days to assess the readiness, clarity of scope submitted for accreditation, documents and their implementation, knowledge and understanding of the applicant's requirements for the first pre-assessment before proceeding with the on-site assessment without considering findings from this pre-assessment for granting laboratory accreditation. After the pre-assessment, 30-day period is provided for corrective action any findings from the date of the closing meeting.
- On-site assessment: 2-3 days to assess compliance and effectiveness of implementing quality management systems and competent the laboratory's ability to perform activities within the scope applied for accreditation. After the on-site assessment, 90-day period is provided for corrective action any nonconformities and observations from the date of the closing meeting.

2.6 Type of the laboratory

○ Public health laboratory (ISO/IEC 17025)

( ) food ( ) drug ( ) cosmetics

( ) medical device ( ) household chemicals products

( ) veterinary ( ) forensic ( ) sensory analysis

( ) Other, please specify.....

○ Medical laboratory (ISO15189)

○ Medical laboratory: Requirements for safety (ISO 15190)

○ Other type of laboratories (please specify) .....

2.7 Accreditation purpose

○ for consideration in the process of product registration

○ for export

○ for testing services ☐ External customer ☐ Internal customer (exclude affiliated company)

○ Other, please specify.....

Part 2 Specific information for accreditation

3. Test item submitted for accreditation * Please specify the details clearly.

(additional sheet of paper or new typing are accepted, but please use the specified table format and listing the items to be tested)

(1) No.	(2) Status	(3) Type of Sample	(4) Test	(5) Method	(6) Test procedure	(7) Type of performed	(8) Principle / Technique / Equipment	(9) Workload, No. of samples per year	(10) The evaluation of laboratory competency 1. Proficiency testing, PT 2. Interlaboratory comparisons 3. Performance testing	(11) For official only: Name of technical assessor
	New/ Re/ Ext/ Sur								☐ **Proficiency testing (PT):** Matrix : …… Test : …… Provider : …….. Date : …… Result : (please specify the result and value i.e. pass, z-score = …. etc.) ☐ **Interlaboratory comparisons:** Matrix : …… Test : …… Provider : …….. Date : …… Result : (please specify the result) Number of participate lab =..... ☐ **Performance testing:** Matrix : …… Test : …… Date : …… Result : (please specify the result) Number of participate person =.....	

Note : The details of the items requested for accreditation ▤ Further information in G 07 15 018

- Clause 2 Specify the status:
  - ✓ New = New accreditation
  - ✓ Re = Re-assessment
  - ✓ Ext = Extended scope
  - ✓ Sur = Surveillance
- Clause 3 Specify the type of sample
- Clause 4 List the tests requested for accreditation i.e. Cadmium, *Staphylococcus aureus* etc.
- Clause 5 Specify the test method, referring to the reference used. For ISO/IEC 17025 and ISO 17034 refer to G 07 15 016.
- Clause 6 Specify the document code for the test method used by the laboratory for each test items.
- Clause 7 Specify types of tests performed, as follows:
  - ✓ Qualitative analysis: Specify whether it is a screening test, confirmation test, or identification test, aligning with the actual testing type conducted by the laboratory.
  - ✓ Quantitative analysis: Specify if it is a determination test.
- Clause 8 Specify the principles or techniques used in testing with regard to specific technique names i.e. HPLC technique, PCR technique, etc.
- Clause 9 Workload: Specify the quantity of tested samples until the application submission date, excluding workload forecast. The samples must have entered the processing workflow, from sample receipt to result reporting. To be eligible for accreditation, a laboratory shall test each test items at least one sample every year. If there are no samples, the application will not be accepted and not be included in the scope.
- Clause 10 The laboratory must assess its proficiency according to N 07 15 003 The medical laboratory shall also comply with the N 07 15 029, as follows:

  1. Participation in Proficiency Testing (PT)

  2. In case that the PT providers are not available, the laboratory shall carry out the interlaboratory comparisons. If more than 3 participating laboratories, specify the provider and the number of participants. If 3 or fewer participating laboratories, list all participating laboratories.

  3. In case that the PT providers and interlaboratory comparison are not available, the laboratory shall carry out to compare the test results or measurand by means of the laboratory's performance assessment between analysts of the laboratory, as follows:
     - ✓ Develop an action plan covering the requested accreditation scope.
     - ✓ Submit assessment results with attached documents.
     - ✓ If the result is unsatisfactory, laboratory shall submit corrective action documents.
     - ✓ Interlaboratory comparison

Further information

G 07 15 016 G 07 15 018 N 07 15 003 N 07 15 029

4. Details of medical laboratory sample collection site. (Include inside, outside branch and mobile unit)

Name of sample collection site such as laboratory, outpatient units, various patient wards, laboratory branch, and mobile units.

Location such as floor, building, community health center, hospital, clinic branch.

No.	Name of sample collection site	Location	For official only: Name of assessor
1			
2			
3			
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10			

Part 3 Quality management system information

5. Structure of laboratory

Please provide the organization chart showing

- the overall organizational structure showing the relationship with all relevant units.
- The laboratory structure illustrating the linkage from the overall organizational structure to the laboratory structure.
- The laboratory structure must include lines indicating the relationship between quality management, technical management, and various support services.

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6. Flow chart of laboratory

Details of the flow chart of laboratory operation map beginning with the process area of sample receipt, sample preparation, analysis area until the end process.

7. Personnel

Supervisor and analyst names (who engaged in every step of the method) and work history.

(additional sheet of paper or new typing are accepted, but please use the specified table format)

(1) No.	(2) Name - Surname	(3) Position	(4) Responsibility	(5) Qualification	(6) Experience/ Year	(7) Accredited test that assigned for approved signatory	(8) Professional licenses

Note:

- Clause 1 Indicate the asterisk (*) symbol at No. of the names who assigned to sign the test reports utilizing the accreditation symbol of BLQS.
- Clause 4 Specify abbreviated roles as follows:

  Tester refers to individuals responsible for examination of samples and/or reporting test results in the respective test.

  Reviewer refers to individuals responsible for reviewing test results.

  Authorizer refers to individuals responsible for authorizing test results.
- Clause 7 Specify the test items linked to Part 2 Specific information for accreditation and Part 3 Quality management system information. This can be indicated either by the sequence number from Part 3 or by the test item name.
- Clause 8 Professional licenses include for doctors, pharmacists, medical technologists, veterinarians etc.

8. Quality management system

8.1 The date of current internal audit and specify the cycle (Cycle ..... / Year .....)

……..

The date of closed out of internal audit. ……...…….....

8.2 The date of current management review and specify the cycle (Cycle ..... / Year .....)

…….....

8.3 Number of complaints since last year. Please specify a description of the complaint: .....

…….....

8.4 The date of current risk management .....

8.5 There are decision rules policy and reporting statements of conformity policy. (For public health laboratory).

❑ Yes (attach documents in Part 4) ❑ No

9. Reference material, Reference standard and equipment that affect the accuracy of test results *(Please record in ordering: reference material, reference standard, equipment that shall calibrate)*

Reference material, Reference standard/ Equipment	Lot/Model	Responsible person	Calibration frequency	Date of last calibration	Name of calibration service

Part 4 The documents attached to the accreditation application

With this request, I have enclosed 1 set of supporting documents as follows:

For laboratory (please specify)	No.	List of attachments	For official only		
			Yes	No	Remark
❑	1)	Location maps of the laboratory and nearby landmark building			
❑	2)	The flow chart of laboratory operation map beginning with the process area of sample receipt, sample preparation, analysis area until the end process including collection sites.			
❑	3)	The certificate of registration as a legal entity with registration purposes, and authorized personnel name of a Juristic person (signed to certify true copy)			
❑	4)	The trade registration or the commercial registration (signed to certify true copy)			
❑	5)	Government act of establishment or regulation (signed to certify true copy)			
❑	6)	License to operate a sanatorium (For medical laboratory) (signed to certify true copy)			
❑	7)	License to management of a sanatorium (For medical laboratory) (signed to certify true copy)			
❑	8)	Power of attorney for the applicant. The evidence of authorizing representative and enclosed with 30 Baht of revenue stamp. (Original copy) (additional details in Note 1: Applicant Information)			
❑	9)	House registration and identification of the applicant (in case of foreign laboratory)			
❑	10)	Current copy of master list of documents			
❑	11)	Quality manual			
❑	12)	Work procedure			
❑	13)	Test method			
❑	14)	Copy of all referenced documents for each requested item of accreditation			
❑	15)	Result of method validation/ method verification for the requested scope of accreditation			
❑	16)	Documents indicating the establishment of decision rule and reporting statements of conformity (if there is a policy)			
❑	17)	Documents demonstrating the calculation of measurement uncertainty covering the requested scope of accreditation			

For laboratory (please specify)	No.	List of attachments	For official only		
			Yes	No	Remark
❑	18)	Results of proficiency testing / Interlaboratory comparison / laboratory's performance assessment between analysts of the laboratory			
❑	19)	Staffs and qualifications			
❑	20)	Major equipment calibration			
❑	21)	Reference materials			
❑	22)	Sample collection manual specified in the service agreement			
❑	23)	Example of test report with accreditation symbols			
❑	24)	Internal audit			
❑	25)	Management review			
❑	26)	Risk and opportunities			
❑	27)	A set of hard copy documents (separate sets of documents for each test item requested for accreditation) and electronic files in Handy drive, CD/DVD, or Google drive format of all submitted documents (separate folders for each test item requested for accreditation in a readable file format (Document No. 14) to 18) shall be submitted as one set of documents/files separated by test method. Except for the BLQS form, which shall be submitted in 2 formats: MS-Word and PDF).			
The attached document for medical laboratory according to ISO 15190 standard					
❑	28)	The training record of safety and ISO 15190 requirements for laboratory safety officer			
❑	29)	Appointment letter of the laboratory safety officer specifying duties and responsibilities			
❑	30)	Laboratory safety manual			
❑	31)	Plan for infection control			
❑	32)	Biological agents and their risk classification 1-4			
❑	33)	Safety program 1) Audit / Inspection report 2) Review / Evaluation report			
❑	34)	Record 1) Incident record 2) Risk assessment analysis 3) Immunization status			

For laboratory (please specify)	No.	List of attachments	For official only		
			Yes	No	Remark
Other attached documents					
❑	35)	.....			
❑	36)	.....			
❑	37)	.....			
❑	38)	.....			
❑	39)	.....			

Result of document check

Document received from: ☐ Authorized person from the CAB ☐ Parcel post

☐ All of documents are accepted to fulfill the requirement for accreditation.

☐ Shall submit additional documents fulfill the requirement for accreditation which are as following:

……

……

Check by (BLQS staff) ……..…….

(…….)

Position ……..…….

Document complete date ……..……..

☞ **Declaration**

1) I hereby commitment to follow the Policy, Requirements and Conditions for the Medical and Public Health Laboratories Accreditation (R 07 15 001), Policy and Conditions for the Use of an Accreditation Symbol or a Statement to Claim Accreditation Status (N 07 15 009) and the additional requirements of the BLQS.
2) I shall pay all fees and costs for the accreditation process irrespective of the eventual granting of accreditation;
3) I shall provide access to personnel, locations, equipment, information, documents and records as necessary for the assessment and maintenance of the accreditation;
4) I shall provide access to the information of independence level and impartiality of the laboratory from its related bodies, where applicable;
5) I shall arrange the witnessing of laboratory services as requested;
6) I shall notify BLQS in writing immediately when there is a change of major issues, that affect application competency, such as change on trade regulations, change on organization status, re-organization, changes on key person on management, change on personnel or method or equipment or facility or work environment and other important resources that may have a significant impact on the scope already accredited;
7) I shall use the certificate and accreditation symbol according to the criteria and condition defined by BLQS without utilizing them in the way cause deterioration or misunderstanding, misleading or exaggerating the accreditation scope. Disobedience will cause BLQS to consider a reduction of accreditation scope, suspension or withdrawn of its certificate, or carry out any other appropriate means;
8) In the case that the certificate was suspended, cancelled, withdrawn, or did not get the certificate renewal, the applicant discontinues its use of all advising matters or referral to the accreditation;
9) I shall assist BLQS in the investigation and resolution of any complaints made by third parties about the accredited activities and submit such related documents to BLQS upon request.

I hereby certify that the undersigned is authorized to take any action on behalf of the laboratory/company and the information provided herein is correct to the best of my knowledge and belief. I have read, understand and agreed to follow the terms and condition of the agreement.

Signature of CAB ……

Name of CAB's authorized representative (……)

Position ……

Date: ……

☞ (Affix Company Seal Here, if any)

☞

Signature of BLQS staff ……

Name of BLQS designated person (……)

Position ……

Date: ……