Policies, Requirements and Conditions for Biobank Accreditation

1. Biobanking scope

1.1 Human

1.2 Animal

1.3 Plant

1.4 Microorganisms

2. Definitions and abbreviation

2.1 Biobank Accreditation

Procedure by which the BLQS-DMSc gives formal recognition that the biobank has the management system and competency complying with the related international standards and the BLQS-DMSc policy, requirements and conditions for Biobank accreditation on its specific tasks listed in the scope of accreditation for research and development, which does not apply to biological material intended for food/ feed production, laboratories undertaking analysis for food/ feed production, and/ or therapeutic use.

2.2 Biobanking

Process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analyzing and distributing defined biological material as well as related information and data.

2.3 Assessment Report Reviewer

Assessment report reviewer for biobank is responsible for reviewing, evaluating and approving a summary report of biobanking assessment from assessor before proposing to the Biobank Accreditation Committee (BAC).

2.4 Biobank Accreditation Committee

Biobank accreditation committee is responsible for making a decision on granting, maintaining, extending, reducing, suspending and withdrawing accreditation of biobank.

2.5 Proficiency Testing (PT)

Proficiency testing (PT) is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

2.6 Interlaboratory Comparison (ILC)

Interlaboratory Comparison is organization, performance and evaluation of measurements or tests on the same or similar items by two or more biobank in accordance with predetermined conditions.

2.7 Biobank's performance assessment in process or test (PFT)

Biobank's performance assessment in process or test is one of the tools used to evaluate the biobank's performance by mean of intercomparison of process or test results between personnel or using other mechanism for evaluation biobank's performance, including the use of:

a) certified reference materials, where available, produced by a reference material producer fulfilling the requirements of ISO 17034;

b) samples previously examined;

c) samples previously shared with other biobanks;

d) control materials that are tested regularly in EQA programs.

2.8 Remote assessment

Remote assessment of the physical location or virtual site a biobank.

Note 1: A virtual site is an online environment allowing persons to execute processes, e. g. in a cloud environment.

3. Qualification of the biobank applicant

The biobank must be legal entity or part of a legal entity that performs biobanking. The biobank may comprise permanent biobank facilities, with or without sites away from its permanent facilities.

4. General requirement

4.1 The authorized management of the biobank or the authorized representative shall sign the application form. The biobank shall attach the evidence of authorizing representative and enclosed with 30 bath of revenue stamp.

4.2 Each applicant must nominate a senior staff member who will represent one in all nominations in all dealings with BLQS-DMSc. This person shall take responsibility for communication between top management / within the organization or biobank, and BLQS-DMSc.

4.3 All details of the quality management system and the implementation document, which are fulfill the requirements of the BLQS-DMSc, shall be submitted with a current copy and electronic file which easily search identical name file. BLQS-DMSc will terminate the application if the documents are not completed within 180 days, after the date of submitting the application.

4.4 The biobank shall comply with the accreditation procedure and shall pay fee as scheduled and conditioned by BLQS-DMSc.

4.5 The biobank shall corporate with the assessors in the following: -

4.5.1 Permit the access to the biobank personnel, locations, equipment, information, document and records.

4.5.2 Prepare for biobank activity or test sample and hand on activity for witness as requested by the assessor.

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

4.6 The administrators and the staff have to work independently and have no conflict of interest that may adversely affect the quality of their works.

4.7 In case that an on-site assessment is not applicable, BLQS shall use another assessment technique to achieve the same objective as the on-site assessment being replaced and justify the use of such techniques (e.g. remote assessment). For details on the requirements for remote assessment, please refer to the supplement requirements for document review and remote assessment, N 07 15 031.

4.8 BLQS shall inform CABs and interested parties of any changes to its accreditation policies and requirements through its official website (https://blqs.dmsc.moph.go.th/page-view/626). In cases where cross-border technical constraints or firewalls prevent access to websites, BLQS shall ensure the direct delivery of essential documents via email or synchronized file-sharing services (e.g., Google Shared Drive, OneDrive, or designated digital platforms). All accredited CABs are required to acknowledge and implement these revised requirements accordingly.

4.9 BLQS-DMSc may reduce the scope or terminate the accreditation when the biobank does not perform as described in clause 7. (Obligations for the accreditation biobank) or there is any indicating to demonstrate that the scope of accreditation is not complied with the requirements of the standards under the consideration of the assessors or assessment report reviewer or the biobank accreditation committees.

4.10 In case that applicant (biobank) is in the process of accreditation or has already been accredited by the BLQS-DMSc and the biobank intends to withdraw the accreditation, the biobank shall inform the BLQS-DMSc, officially, in written document, to the director of BLQS-DMSc. The biobank cannot refund fee for accreditation.

4.11 The biobank shall declare and carry out its activities in such a way as to meet the relevant national and regional regulations.

5. Quality requirement

5.1 The biobank shall implement the quality management system according to the ISO 20387.

5.2 The biobank shall participate in proficiency testing program (s) or interlaboratory comparison or Biobank's performance assessment in process or test (PFT), frequency in participation depend on the rounds of the providers or at least once a year.

5.3 The biobank shall conduct internal audit and review its quality management system at least once a year.

6. The accreditation process

6.1 The biobank shall submit the application to the BLQS-DMSc with the list of relevant documents as mentioned in Appendix 1.

6.2 After the acceptance of the application, the BLQS-DMSc will proceed as following:-

6.2.1 Examines the completeness of the documents, the result of proficiency testing or interlaboratory comparison or biobank's performance assessment in test, and then inform the applicant to pay the fee as indicated by BLQS-DMSc.

6.2.2 The biobank shall submit relevant ethical approvals compliance with applicable regulatory of human and /or animal scope.

6.2.3 Appoints the assessors after all of documents are ready for accreditation.

6.2.4 Pre-assesses, if it is required by the applicant, the biobank is notified of the date, time, and the assessors' name. The assessors will assess the Quality system documents, and related documents at the biobank premise as pre-assessment. BLQS-DMSc will inform the name of assessors and the date of pre-assessment before conduct the assessment.

6.2.5 Inform the pre-assessment results to the biobank by sending the official report of pre-assessment.

6.2.6 Informs the name of the assessors and appoint the date of the on-site assessment after the applicant biobank submits the corrective action form of the pre-assessment. In case that applicant biobank does not request for pre-assessment the processes in the item 6.2.3 and 6.2.4 are omitted. BLQS-DMSc will inform the name of the assessor and appoint the date of the on-site assessment, together with the accreditation fee and then the assessment will be carried out.

6.2.7 The biobank shall correct all nonconformities in the timescale of the requirements for accreditation process of the BLQS-DMSc. The duration for corrective action begins on the date of closing meeting for the assessment. The table of findings (F 07 15 038), corrective actions and supportive evidences, both in the electronic file and the current copy are to be sent to BLQS-DMSC. The timescale of corrective action for the nonconformities form the various assessments are mentioned as following:-

6.2.7.1 For pre-assessment, the biobank shall submit the corrective action within 30 days. In case that the biobank cannot complete the corrective action within 30 days, the biobank can request for extending the duration of corrective action for another 30 days to the Director the BLQS- DMSc, in written, with the reason and the approximate date for completion of all corrective action of nonconformities. After that date, BLQS-DMSc shall immediately conduct the on-site assessment.

6.2.7.2 For on-site assessment of the initial of accreditation, the corrective action for nonconformities shall be carried out within 90 days. In case the biobank cannot complete the corrective action within 90 days, that biobank can request for extending the duration of corrective action for another 30 days, in written to the Director of BLQS-DMSc, with the reason and the approximate date for completion of corrective action. However, the duration for proposing of all corrective actions of nonconformities shall be done within 120 days from the date

of closing meeting for the assessment. The nonconformities of scope of accreditation, which have not been corrected and closed within the timeframe, are withdrawn or rescinded.

6.2.7.3 For surveillance, re-assessment and extended scope of the accreditation, the biobank shall carry out the corrective actions of nonconformities within 30 days. In case the l biobank cannot complete the corrective action within 30 day, that biobank can request for extending the duration of corrective action for another 30 days, in written to the Director of BLQS-DMSc, with the reason and the approximate date for completion of corrective action. If the biobank cannot complete the corrective action and closed out nonconformities within the timeframe given, it shall be suspended the accreditation. If the nonconformities of scope of accreditation have not been corrected and closed after suspension of accreditation interval, then those scopes are withdrawn or rescinded.

6.2.7.4 In case of the biobank cannot submit the evidence for corrective action of nonconformities from the assessment according to 6.2.6.2 or 6.2.6.3 within the timeframe given, and not inform in written with the reason to the Director of BLQS-DMSc. The BLQS-DMSc shall withdraw those scopes of accreditation which are not closed-out the nonconformities.

6.2.8 BLQS-DMSc issues the certificate of accreditation after the Biobank Accreditation Committee grants the approval. The certificate of accreditation signed by the Director of BLQS-DMSc. The issued date is the date of the Biobank Accreditation Committee grants the approval.

6.2.9 If the biobank submitted the application for re-assessment earlier before 120 days of on-site reassessment schedule, the expired certificate of accreditation shall be valid until the Biobank Accreditation Committee grants the approval.

6.3 The accredited biobank will receive certificates in Thai and English languages. The accreditation certificate is valid for 4 years from the issued date. The accredited biobank can verify its expiration date from the certificate and on BLQS-DMSc website (http://blqs.moph.go.th).

6.4 If the accreditation certificate is lost, the biobank can file for request a replaced one. Both of the governmental or private biobank shall submit the official request memorandum to the Director of BLQS-DMSc enclosed with the police report for lost document within 15 days of the incident date. Payment shall be following as fee schedule determined by BLQS-DMSc.

6.5 In case of damaged accreditation certificate, the biobank can file for request a replaced one. The biobank shall submit the official request memorandum to the Director of BLQS-DMSc enclosed with the damaged certificate. Payment shall be following as fee schedule determined by BLQS- DMSc.

6.6 For editing in details of accreditation after assessment, the biobank shall submit the official request memorandum to the Director of BLQS-DMSc enclosed with the edited remark of application form, evidence, principle reference, and reasonable description for non-significance changes from previous assessment. In case for editing in details of certificate of accreditation, accredited biobank shall pay the certificate fee following as fee schedule determined by BLQS-DMSc.

7. Obligation for the accredited biobank

7.1 The accredited biobank shall commit to fulfill continually the quality management system and technical competence of the accreditation set for the areas, scope which accreditation is sought or granted compliance with the international standard and BLQS-DMSc's requirements at all time of accreditation. This included agreement to adapt to change in the BLQS-DMSC's requirements for accreditation.

7.2 Cooperate to enable BLQS to verify fulfilment of requirements for accreditation.

7.3 Provide access to personnel, locations, equipment, information, documents and records as necessary for the assessment and maintenance of the accreditation;

7.4 Provide access to the information of independence level and impartiality of the biobank from its related bodies, where applicable.

7.5 Arrange the witnessing of biobank services as requested.

7.6 Have, where applicable, legally enforceable arrangements with their customers that commit the customers to provide, on request, access to BLQS assessment teams to assess the biobank's performance when carrying out testing activities at the customer's site.

7.7 Uses accreditation statements, the accredited biobank shall inform BLQS-DMSc of the intension to use the accreditation statements.

7.8 Correctly uses the statements. BLQS-DMSc will take necessary actions against the accredited biobank or individuals who misused statements. In the way of incorrect references or misleading or misrepresentation, for example using accreditation statements for unaccredited scope and/or unauthorized approved signatory. In these cases, the accredited biobank shall be suspended of accreditation for 90 days and might be sentenced by law.

7.9 Shall immediately stop using or shall not claim to its accredited status for the activities which are suspended withdraw or reduced the scope of accreditation. Such misusages might result in legal responsibility. The accredited biobank shall inform its affected customer of the suspension, reduction or withdrawal of its accreditation and the associated consequence without undelay.

7.10 Shall not do anything which may mislead that the granted accreditation is BLQS-DMSc certification for the product quality.

7.11 Shall inform BLQS-DMSc, within 15 days, if there is any change from the application forms.

7.11.1 Legal status or business status and organization chart.

7.11.2 Top management or Biobank management who make a decision for the organization management.

7.11.3 Policy and activity according to the scope of accreditation. The biobank shall provide BLQS-DMSc with copies of the changes.

7.11.4 Personnel, equipment, environment that have an effect directly to the quality of biobanking.

7.11.5 Approved signatories for the accredited scope or key personnel.

Note: If the biobank loses its sole approved signatory, the accreditation status of the biobank will be suspended.

7.11.6 The claim or the use of accreditation statement.

7.11.7 Others changes that may affecting the competency of the biobank .

7.12 Pay fees as determined by BLQS-DMSc.

7.13 Shall assist BLQS to provide the facts in the investigation and resolution of any complaints made by third parties or interested parties on the biobank's accredited scope.

7.14 Collection and storage of all quality documents for at least 5 years, therefore, the documents can be traceable. The documents can be on various media, such as hard copy or digital.

8. Surveillance

8.1 On-site surveillance shall be carried out at intervals not exceeding two years of the accreditation cycle. The accredited laboratory shall submit the quality documents for surveillance assessment according to application forms No 1, F 07 15 005, at least 7 months before the certificate reaches 2 years of age, and the surveillance assessment should be conducted at least five (5) months before the certificate reaches 2 years of age. Failure to complete the on-site assessment within the designated time frame may result in suspension the accreditation..

8.2 Another surveillance shall be done, if it is the decision making from the biobank accreditation committees, or as a result of complaint, or there is any evidence indicates that the accredited biobank may not continuously maintain their quality management system in previous assessment. The accredited biobank shall submit the quality documents for surveillance assessment according to Appendix 1 earlier before 3 months of the decision-making schedule.

9. Reassessment

9.1 If the accredited biobank intends to reaccredit, the complete application forms with required documents for reassessment shall be submitted earlier, before 7 months of the expiry date the expired certificate of accreditation shall be valid until the Laboratory Accreditation Committee grants the approval. The renewal assessment shall be established within 5 months of the expiry date. Failure to meet this condition shall be considered as the biobank does not intend to reaccredit. The accreditation will be ended up as the expiration date on the certificate.

9.2 The biobank shall submit the complete document as defined in Appendix 1 with reassessment application forms to BLQS-DMSc.

9.3 The biobank shall pay for accreditation fee as indicated.

9.4 In case reassessment that process is ongoing, as follow as:

9.4.1 If the laboratory has complied with all BLQS policies and conditions, including document submission, assessment, and corrective action for nonconformities within the timeframe, but delays occur within the BLQS scope of responsibility (such as the review of corrective actions by assessor or approval of the grant by Laboratory Accreditation Committee). BLQS shall issue a formal letter of re-assessment status.

- If the certificate is approved before the expiration date, the effective date of the new certificate will remain the original date and be extended for another 4 years.
- If the certificate is approved after the expiration date,cthe effective date shall be

the date on which the Laboratory Accreditation Committee grants approval, and it will be extended for another 4 years

9.4.2 If the laboratory has not complied with all BLQS policies and conditions, including document submit, assessment, and corrective action for nonconformities within the timeframe. The laboratory shall be a temporary suspension and the effective date shall be the date on which the Laboratory Accreditation Committee grants approval, and the expiry date shall be the same expiry date as the previous certificate.

10. Extension scope of accreditation (Extending accreditation)

Accredited biobank can request for an extension the scope of an accreditation to BLQS-DMSc under the timeframe as follows:

10.1 The accredited biobank shall apply for extension scope of accreditation at the same time of re-assessment and pay for accreditation fee as indicated, and the biobank shall submit the document for extended scope and re-assessment according to clause 9.2. If the biobank submitted the document for extended scope to be late from the timeframe given for re-assessment, the BLQS-DMSc shall appoint the assessors for re-assessment only. The extended scope shall be separate and the biobank shall pay for accreditation fee as indicated.

10.2 In case that accredited biobank needs to apply for extension scope of accreditation before the time of reassessment, it can request an extension to scope at any time. The accredited biobank shall submit the application with the related quality documents to BLQS-DMSc. The BLQS-DMSc shall carry out the on-site extension in the same manners as in the initial assessment. The biobank shall pay for accreditation fee as indicated. The expiry date of certificate for extension scope shall be the same expiry date of previous certificate.

10.3 In case of the biobank, an extension scope shall be assessed for at the same time as reassessment according to clause 9.4.

11. Withdrawal / Suspension of the accreditation

11.1 Suspension of accreditation

The Director of BLQS-DMSc will declare a temporary suspension of the accreditation as follows:

11.1.1 The biobank does not follow the policy, requirements and conditions of the BLQS-DMSc such as fees were not paid, the corrective action documents were not proposed

within a given timeframe, the assessment documents were not proposed within a given timeframe.

11.1.2 The biobank cannot close out nonconformities and reaccreditation within a given timeframe. If the biobank cannot correct and close out nonconformities within a given timeframe again, BLQS-DMSc will consider withdrawing or reducing the scope of the accreditation, accordingly.

11.1.3 In accordance with clause 11.1.1-11.1.2, the laboratory shall be temporary suspension for 3 months. If the laboratory cannot lift the temporary suspension within 3 months, it shall be withdrawal or reducing accreditation.

11.2 Withdrawal of accreditation

BLQS-DMSc will withdraw the accreditation under the following circumstances.

11.2.1 The biobank has become bankruptcy by court order.

11.2.2 Any practice that violated or did not comply with the Act for "National Standards Act, B.E. 2551 (2008). Published in the Royal Thai Government Gazette. Volume 125, Part 42 A, Published Date 4th March A.D. 2008" and the BLQS-DMSc's requirements.

11.2.3 If there is evidence of fraudulent behavior, intentional provision of false information or conceals information.

11.2.4 The accredited biobank terminates its business.

11.2.5 The certificate is expired and the biobank does not intend to reaccredit.

The biobank shall inform the termination by officially document to BLQS-DMSc within 3 official days after acting as clause 11.2.1, 11.2.2 or 11.2.3. The biobank can appeal for withdrawal within 15 days after receiving the withdrawal official letter.

11.3 Voluntary Withdrawal

The accredited biobank can request for withdraw from the accreditation program. The biobank shall inform the termination by officially document to BLQS-DMSc within 3 official days. They shall immediately stop using or shall not claim BLQS-DMSc accreditation symbol or reference to its accredited status for the activities.

12. Confidentiality

12.1 All information provided by any applicants in relation to preliminary enquiries or to an application for accreditation and all information obtained in the course of, or in connection with,

an assessment of an accredited biobank shall be completely confidential.

12.2 BLQS-DMSc shall not disclose confidential information about a particular accredited biobank without written consent of the accredited biobank, except where the law requires such information to be disclosed without such consent. All personnel, assessor and committee of BLQS shall be aware of and abide by this requirement for confidentially. They are required and sign the formal undertaking for maintain confidentially and impartially and declaration of conflict of interest.

13. Appeal

13.1 BLQS establish guidelines for appeals for Laboratory Accreditation, G 07 15 007.

13.2 The appeal for any decisions shall be submitted in written to the Chairman of the Appeal Committee within 15 days upon receipt of the withdrawal letter.

13.3 The decision of the Appeal Committee shall process within 3 months period.

13.4 The Appeal Committee's decision is a final.

13.5 During the appeal, the accreditation is still valid.

14. The use of a statement to claim accreditation status

14.1 Biobank shall inform the BLQS-DMSc of the accreditation statement.

14.2 The statement shall not be abused, misused, or misleaded in the accreditation. Misuse of those statements to their accreditation status or in any form of the BLQS-DMSc, Policy may be also legal penalties. The accredited biobank shall be suspended of accreditation for 90 days if it uses the accreditation statements out of its scope of accreditation, may be punished according to the law.

15. Miscellaneous

15.1 BLQS-DMSc may amend the Policies, requirements and conditions for a biobank accreditation stated in the document and other accreditation criteria from time to time as it sees fit. BLQS-DMSc will inform any changes of requirements and conditions on BLQS-DMSc website (http://blqs.dmsc.moph.go.th), which shall be corrected adjusted within the time frame.

15.2 BLQS may investigate any complaint made to BLQS by the third parties against an accredited biobank concerning activities included in its scope of accreditation. The biobank shall provide information to BLQS upon request and shall cooperate with BLQS for the purpose of investigating the complaints.

15.3 BLQS reserves the right not to disclose any complainant.

15.4 The BLQS-DMSc shall not take any responsibility if the biobank does not conform to the policy, requirements and conditions of the BLQS-DMSc.

15.5 BLQS shall not be liable to the accredited biobank for any losses, damages or expenses including injury to reputation suffered by the accredited biobank and/third parties, arising directly or indirectly form the accreditation of the accredited biobank, use of the accreditation statement, assessment activities carried out on the accredited biobank by BLQS, its representatives and employees except if such loss or damage results from negligence by BLQS.

15.6 The accredited or suspended or withdrawn biobank names, scope, activity and accreditation number will be announced in the website (http://blqs.dmsc.moph.go.th). The certification format of accreditation as mentioned in Appendix 2.

15.7 Interested party shall submit the application to BLQS-DMSc, at the Ministry of Public Health, Nonthaburi.

16. Responsibility of the accreditation committees and the assessment report reviewer committees.

16.1 Biobank Accreditation Committee

The responsibilities of this committee are as follows:

16.1.1 To approve on granting, maintaining, extending, reducing and suspending accreditation of biobank in complying with ISO 20387, as well as the policy, requirements and conditions of biobank accreditation.

16.1.2 To approve on the withdrawal of the biobank accreditation in case that the biobank is out of business, has become bankruptcy by court order and any practice that violate or do not comply with the BLQS-DMSc requirements.

16.1.3 To delegate other missions.

16.2 Assessment Report Reviewer for Biobank Accreditation.

The responsibilities of the reviewer are as follows:

16.2.1 To review the assessment report or biobanking activities complying with ISO 20387 and the policy, requirements and conditions for the accreditation before proposing to the biobank accreditation committee.

16.2.2 To delegate other missions.

17. Appendix 1

Submitted documents for accreditation application are as follows:

17.1 Application Form No.14 [F 07 15 180] - Application form for Biobank Accreditation

17.2 Application Form No.15 [F 07 15 181] - ISO 20387: 2018 checklist

17.3 Two sets of location maps of the biobank and nearby landmark building.

17.4 Copy of the certificate of registration as a legal entity with registration purposes, and authorized personnel name of a Juristic person.

17.5 Copy of the trade registration of the commercial registration.

17.6 Power of attorney for the applicant. The evidence of authorizing representative and enclosed with 30 Bath of revenue stamp.

17.7 Copy of identification of the applicant (For foreign biobank).

17.8 Copy of Government act of establishment or regulation.

17.9 Copy of relevant ethical approvals compliance with applicable regulatory of human and/or animal scope.

17.10 Nomination a senior staff member as a representative in all dealings with BLQS-DMSc.

This person shall take responsibility for communication between top management/ within the organization biobank, and BLQS- DMSc.

18. Appendix 2

18.1 Certification format of biobank accreditation (ISO20387)

(Certificate of accreditation)

Bureau of Laboratory Quality Standards Ministry of Public Health

This is to certify that The Biobank of

..... Accredited biobank name .....

..... Address .....

has been accepted as an accredited biobank complying with the ISO 20387:.....Year of edition.....
and the requirements of the Bureau of Laboratory Quality Standards
The biobank has been accredited for specific scope of

.....type of scope.....

.....Signature.....

(.....Name – Surname.....)

Director of Bureau of Laboratory Quality Standards

Date of Accreditation .....Date/Month/Year.....

Valid Until.....Date/Month/Year..... Accreditation No. ...../.....

(Attachment of certificate of accreditation)

The Biobank of ...Accredited biobank name... **has been accepted as an accredited biobank in the specific scope as the following scopes.**

No.	Categories	Subcategories	Activities	Storage Conditions	Method(s)

Remark: "This certificate does not apply to biological material intended for food/feed production, laboratories undertaking analysis for food/feed production, and/or therapeutic use."

Bureau of Laboratory Quality Standards

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Accreditation Number ...../.....

Revision No. ... **Date of Accreditation :** .....Date/Month/Year.....

Date Issued/Date Revised .....Date/Month/Year.... **Valid Until :** .....Date/Month/Year.....

Reviewed by Head of Laboratory Accreditation Section.....(.....)

19. History of Change

Revision No.	Documentation Changes	Prepared/ Revised by	Date Issued
00	- New	Siratcha Dulyakorn	13 June 2020
01	- Updated approver	Siratcha Dulyakorn	12 March 2024
02	- Add details Biobank Accreditation (clause 2.1) - Add "The biobank shall submit relevant ethical approvals compliance with applicable regulatory of human and /or animal scope" (clause 6.2.2) - Appendix 1 Add Submitted documents (clause 17.9) - Appendix 2 Add Remark in Attachment of certificate of accreditation	Siratcha Dulyakorn	9 October 2025
03	- Edited clause 4.8 inform CABs and interested parties of any changes to its accreditation policies and requirements through its official website - Edited clause 8.1 and 9.1 The accredited biobank shall submit the application to the BLQS-DMSc with the listed of relevant documents as mentioned in Appendix 1 earlier before 7 months of the expiry date and an assessment shall be established from within 60 days of the most recent reassessment schedule is 5 months of the expiry date - Edited clause 8.2 submit documents earlier before 3 months of the decision-making schedule	Siratcha Dulyakorn	6 March 2026

Revision No.	Documentation Changes	Prepared/ Revised by	Date Issued
	- Canceled clause 9.4 and edited in case reassessment that process is ongoing. - Added clause 10.3 In case of the biobank, an extension scope shall be assessed for at the same time as reassessment according to clause 9.4 - Added clause 11.1.3 the laboratory shall be temporary suspension for 3 months.		
04	- Edited clause 8.1 On-site surveillance shall be carried out at intervals not exceeding two years of the accreditation cycle. The accredited laboratory shall submit the quality documents for surveillance assessment according to application forms No 1, F 07 15 005, at least 7 months before Ms.Saovanee Aromsook Date Issued April 2026 the certificate reaches 2 years of age, and the surveillance assessment should be conducted at least five (5) months before the certificate reaches 2 years of age.	Siratcha Dulyakorn	