Application form No. 11

A request and specific information for RMP accreditation

☞ **CAB No.** ……..……..……..…….

Date……..……..……..…

☞ ***[Applicants from overseas are required to complete all international applications and supporting documentation must be submitted exclusively in English.]***

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: ……

Apply for the RMP/company:

Name: ……

Address: ……

Telephone Number: …… Fax Number: ……

Website: …… E-mail: ……

Business venture: ……

Nomination of a senior staff member as a representative in all details dealing with BLQS-DMSc:

Contacted name: …… Position: ……

Telephone Number: …… Fax Number: ……

Mobile: …… Line: …… E-mail: ……

Name of key persons:

Top management/RMP management: …… Position: ……

Quality manager: …… Position: ……

Telephone Number: …… Fax Number: ……

Mobile: …… Line: …… E-mail: ……

Technical manager: …… Position: ……

Note: Power of attorney:

For government organizations/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 the grantor of authorization, authorized representative, and two witnesses.
2. The official letter specifies the individual authorized to act and the matter delegated clearly, signed by the Top management.

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

2. RMP information

Legal status

○ Government Organization ○ State Enterprises ○ Public Company Limited

○ Private Company Limited ○ Other (please specify) ……

Date of establishment of RMP: …… **Registration number:** ……

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

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

3. Purpose of request

☞ ○ New accreditation (☐ Request for **Pre-assessment (Voluntary)** ☐ On-site assessment)

○ Surveillance ○ Re-assessment ○ Extended scope ○ Follow-up ○ Extraordinary assessment

4. Type of the RMP:

○ Chemical composition; ○ Biological properties ○ Clinical properties

○ Physical properties ○ Engineering properties

○ Other type of RM (please specify):

( ) food ( ) pharmaceuticals ( ) drugs ( ) cosmetics

( ) medical device ( ) veterinary ( ) forensic sciences ( ) pesticides

( ) household products ( ) others (please specify): ……

5. Accreditation purpose

○ Generally restricted to own use ○ For export ○ For services ○ External customer

○ Internal customer (include affiliated company) ○ Internal customer (exclude affiliated company)

○ Other, please specify ……

Part 2: Specific information for accreditation

6. Scope submitted for accreditation

* Please specify the details clearly. (An additional sheet of paper or new typing is accepted, but please use the specified table format.)

Name of lead assessor (LA) ……..……..

(1) No.	(2) Status	(3) Type (CRM / RM) (#)	(4) Matrix / Artefact / Test analysis (Measurement)	(5) Property / Value / Identity / Characterisation range (including range and uncertainty, if appropriate)	☞ (6) The metrological traceability of the certified value is established through a competent producer that is:	(7) Measurement methods or technical standards (##)	(8) Procedure code number / CoA code number	(9) Workload, No. of RM per year	(10) Approach used to assign property values	(11) For official use only: Name of technical assessor (TA)
1.	New/ Re/ Ext/ Sur				☐ **Traceable to the International System of Units (SI) via:** ○ NMIs with peer-evaluated CMC claims [ ] With peer evaluation (**CRM**) [ ] Without peer evaluation (RM) ○ NMI-designated laboratories [ ] With designation (**CRM**) [ ] Without designation (RM) ☐ **ISO 17034 Accredited** [ ] Accredited (**CRM**) [ ] Non-accredited (RM) ☐ **Using a primary method of measurement without international recognition** (RM) ☐ **Internationally recognized sources (Please attach supporting evidence)** ☐ **Other: ……**					

(#) ***Remarks:-*** *Please also specify* ***C = Category No. A to E****, and* ***S = Sub-category No.*** *and summarized details of RM according to R 07 15 004 Appendix 2.*

(##) ***- The approach used to assign property value*** *reference to the ISO 33405 – Approaches for characterization and assessment of homogeneity and stability and also specify* ***an in-house method****, if RMP doesn't exactly follow the standard method, and please attach the report of method validation, method verification, and estimation of measurement of uncertainty (referred to N 07 15 007).*

7. RM Production flow chart and details (specify all stages/tasks of RM). (* Allowed to re-type or add more attached document but the detail is not less than these.)

✓ Production 1, 2, 7, 8, and 9 RMPs shall not subcontract.

Production (APLAC-TC008)	**Procedure name/code number**	**RMP operates itself**	**RMP uses subcontractors**		
			Subcontractor	**Test item**	**Accreditation**
1. Production planning		✓			
2. Selection of subcontractors (if relevant)		✓			
3. Production control					
4. Material handling, storage and processing					
5. Assignment of homogeneity and stability					
6. Characterization and measurement of property values					
7. Assignment of property values and associated uncertainties		✓			
8. Authorization of property values		✓			

Production (APLAC-TC008)	**Procedure name/code number**	**RMP operates itself**	**RMP uses subcontractors**		
			Subcontractor	**Test item**	**Accreditation**
and associated uncertainties					
9. Authorization of RM documents		✓			
10. Distribution of RM					

8. Collaborators/subcontractors information (* Allowed to re-type or add more attached document but the detail is not less than these.)

No.	**Subcontractor name and address**	**Tasks/activities performed**	**Accreditation held** (where applicable)	**Types of testing / measurement activities**
1				
2				

9. Inter-laboratory exercises for the purpose of assigning property values, where applicable.
(* Allowed to re-type or add more attached document but the detail is not less than these.)

No.	**Type of CRM**	**Characterization**	**Name of compared method(s)**	**Name of compared laboratory(ies)**	**Date of exercises** (DD/MM/YYY)	**Evaluation result** (SI units)	**Attachment**
1							
2							

10. Assessment of homogeneity

CRM / RM name	Number of packages / package size	Repeatability	Standard Uncertainty	
			Value (mean)	u_{bb}
1.				
2.				

11. Assessment and monitoring of stability and their production details

CRM / RM name	Period of study	Number of samples	Standard Uncertainty		**Production volume / Packing size**	**Shelf – life (years)**	**Metrological traceability**
			Value (mean)	u_{lts}			
1.							
2.							

12. Characterization

CRM / RM name	Tested Parameter	Statistics	Number of samples	Standard Uncertainty	
				Value (mean)	u_{char}
1.					
2.					

13. Assignment of property values and their uncertainties

CRM / RM name	Sources of uncertainty	Standard uncertainty	☞ Combine relative standard uncertainty
1.	- u stability (short term / long term) - u characterisation - u homogeneity	- - -	
2.	- u stability (short term / long term) - u characterisation - u homogeneity	- - -	

14. Date of internal audit (DD/MM/YYY)
- Every activity was audited ❑ completely ❑ not yet, but will be done at (DD/MM/YYY) …….
- Date of completely closing out the corrective action request (DD/MM/YYY): ……

15. Date of management review (DD/MM/YYY) ……

16. Date of customer feedback survey (DD/MM/YYY) ……

17. Complaints: Number of titles…… are as described about ……

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☞ **18. In-house Testing Capabilities (No Subcontracting used for testing):**

18.1 Primary Certificed Reference Materials / Reference Materials

No.	*Primary* CRM / RM	Brand name / Lot No.	Assigned value	Standard uncertainty	Expiry date	Attachment
1.						
2.						

18.2 Reference Standards

No.	Reference Standards	Class / Model / Serial No.	Working range	Measurement uncertainty	Calibration date (DD/MM/YYY)	Attachment
1.						
2.						

18.3 Equipment affecting testing results that require calibration

No.	Equipment	Brand name / Model / Serial No.	Measurement range	In-house or External calibration	Calibration date (DD/MM/YYY)	Attachment
1.						
2.						

18.4 Quality Assurance (Proficiency Testing, External Quality Assessment, Interlaboratory Comparison, Intralaboratory Comparison)

Please provide details in Form F 07 15 063 (T)

19. Document, Information and Records:-

They are established, stored, distributed and retained in the form of

No.	Type of document (Both of quality and technical records)	Type of media (Please tick ✓ and specify details)		Retention time
		Hard copy (Please specify format (#))	Electronic media (Please specify details of the computer software program (##))	
1				
2				

(#) **Remarks:**- *e.g.* forms, contracts, worksheets, workbooks, check sheets, control charts/graphs, reports, certificates, statements.

(##) - *e.g.* name, version, validated and in-house developed or off-the-shelf software.

20. Approved signatory (who will sign on the certificates or documentation for users in the form of a statement, analysis report, or information sheet, however named, with accredited RM production) (If any changes from the last list of approved signatories, please separately submit the official letter to BLQS-DMSc with the supporting evidence.)

No.	Name – Surname (Mr./Mrs./Ms./Dr.)	Technical and quality position	Graduated qualification, Major	Experience period	RM production that is assigned to the signatory	Signature of approved signatory
1						
2						

21. Certificates or documentation for users in the form of a statement, analysis report, or information sheet, however named.

- ❑ Please attach a copy of every type of their examples, which will be used in the scope of accreditation.
- Transmission of them by
  - ❑ hard copy or paper document
  - ❑ online computer
  - ❑ electronic or electromagnetic means ……

22. RMP operation site map (drawing the landscape of the production site and identifying the flow chart of RM production). (* Allowed to re-type or add more attached document but the detail is not less than these.)

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Part 3: The documents attached to the accreditation application

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

For RMP (please specify)	No.	List of attachments	For official only		
			Yes	No	Remark
❑	1)	Location maps of the RMP and nearby landmark building			
❑	2)	The flow chart of RMP operation map beginning with the process area of raw material receipt, RM production, test analysis area until the end process.			
❑	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 as a legal entity with registration purposes, and authorized personnel name of a Juristic person (signed to certify true copy)			
❑	5)	Government act of establishment or regulation (signed to certify true copy)			
❑	6)	Power of attorney for the applicant. The evidence of authorizing			

For RMP (please specify)	No.	List of attachments	For official only		
			Yes	No	Remark
		representative and enclosed with 30 Baht of revenue stamp. (Original copy)			
❑	7)	House registration and identification of the applicant (in case of a foreign RMP)			
❑	8)	Application form No. 11 and 13			
❑	9)	Example of RM certificate of analysis using the accreditation symbols			
❑	10)	Copy of all referenced documents for each requested item of accreditation			
❑	11)	Current copy of the master list of documents			
❑	12)	Quality manual			
❑	13)	Work procedure			
❑	14)	Work instructions			
❑	15)	Worksheets / Forms			
❑	16)	Test method			
❑	17)	Customer manual			
❑	18)	Result of method validation / method verification for the requested scope of accreditation			
❑	19)	Documents indicating the establishment of decision rule and reporting statements of conformity (if there is a policy)			
❑	20)	Documents demonstrating the calculation of measurement uncertainty covering the requested scope of accreditation			
❑	21)	Results of proficiency testing / Interlaboratory comparison / laboratory's performance assessment between analysts of the laboratory			
❑	22)	Homogeneity study report			
❑	23)	Stability study report			
❑	24)	Property value characterization report			
❑	25)	Assignment of property values and their uncertainties report			
❑	26)	Certificate of RM and relevant documents			
❑	27)	Staffs and qualifications			
❑	28)	Major equipment calibration			

For RMP (please specify)	No.	List of attachments	For official only		
			Yes	No	Remark
❑	29)	Primary Reference Materials			
❑	30)	Internal audit			
❑	31)	Management review			
❑	32)	Risk and opportunities			
❑	33)	A set of hard copy documents (separate sets of documents for each test item / RM 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 / RM requested for accreditation in a readable file format The BLQS forms shall be submitted in 2 formats: MS-Word and PDF with signature).			
Other attached documents					
❑	34)				
❑	35)				

Result of document check

Document received from: ❑ Authorized person from the CAB ❑ Parcel post ❑ Other: ……

☐ All documents are accepted to meet the accreditation requirement.

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

……..……..

……..……..

Check by (BLQS staff) … …… Document complete date ……..……

Declaration

1. I hereby commit to follow the Policy, Requirements, and Conditions for the Reference Material Producer Accreditation (R 07 15 004), the Policy and Conditions for the Use of an Accreditation Symbol or a Statement to Claim Accreditation Status (N 07 15 009), and any additional requirements of the BLQS.

2. I shall pay all fees and costs associated with the accreditation process, irrespective of whether accreditation is eventually granted.

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 information regarding the level of independence and impartiality of the Reference Material Producer from its related bodies, where applicable.

5. I shall arrange for the witnessing of reference material producer services as requested.

6. I agree to notify BLQS in writing immediately of any major changes that affect the organization's competency, such as changes in trade regulations, organizational status, re-organization, changes in key management personnel, or changes in personnel, methods, equipment, facilities, work environment, or other critical resources that may significantly impact the accredited scope.

7. I agree to use the certificate and accreditation symbol according to the criteria and conditions defined by BLQS. I shall not utilize them in any way that causes misunderstanding, is misleading, brings the accreditation into disrepute, or exaggerates the accreditation scope. Non-compliance may lead BLQS to consider a reduction of the accreditation scope, suspension, or withdrawal of the certificate, or other appropriate actions.

8. If the certificate is suspended, cancelled, or withdrawn, or during the certificate renewal process, the applicant shall discontinue the use of all advertising materials or any reference to the accreditation.

9. I shall assist BLQS in the investigation and resolution of any complaints made by third parties regarding the accredited activities and shall submit all related documents to BLQS upon request.

I hereby certify that the undersigned is authorized to act on behalf of the reference material producer/company and that the information provided herein is correct to the best of my knowledge and belief. I have read, understood, and agree to abide by the terms and conditions of this agreement.

☞ **Signature**	_____	**Signature**	_____
CAB Authorized Person's name	_____	**BLQS Designated Person's name**	_____
Position	_____	**Position**	_____
(DD/MM/YYY)	_____	**(DD/MM/YYY)**	_____

(Affix Company Seal Here, if any)
