



Hong Kong Accreditation Scheme

HOKLAS 019

Application for Reassessment and Surveillance Plan B

Note:

1. Applications for adopting Plan B for a given scope of activities will only be accepted from an accredited laboratory or proficiency testing provider (PTP) at the time when it is providing information for a reassessment of such activities.
2. This form shall be completed by any laboratory or PTP intending to adopt Plan B, irrespective of its current plan.
3. For accredited laboratories or PTPs applying to adopt Plan B, this form shall be completed and returned together with HOKLAS 007 (for non-medical laboratory), HOKLAS 016 (for medical laboratory) or HOKLAS 018 (for PTP).
4. An electronic version of the completed form shall also be provided to facilitate assessment.
5. Before completing this form, applicants should study HKAS Supplementary Criteria No.4 carefully.
6. Applicants must provide all the information requested in this form. Otherwise, the application cannot be accepted.
7. Completing this form is necessary only for laboratories or PTPs intending to adopt Plan B. For laboratories or PTPs intending to adopt Plan C, HOKLAS 020 should be used. Plan A will be adopted for accredited laboratories or PTPs which have not applied for Plan B or Plan C.

HONG KONG ACCREDITATION SERVICE

36/F., Immigration Tower, 7 Gloucester Road, Wanchai, Hong Kong.

Tel : 2829 4840

Fax : 2824 1302

E-mail : hkas@itc.gov.hk

The personal data collected will be used for accreditation purpose only.

To be completed by the applicant

On behalf of _____ (the Organisation),
(Full name of organisation#)

I, _____ (full name of the authorised representative),
having read and understood the document HKAS Supplementary Criteria No.4 hereby apply
to HKAS Executive for adopting the reassessment and surveillance Plan B described in HKAS
Supplementary Criteria No.4 for the scope of accreditation listed in the accompanying
HOKLAS 007 (for non-medical laboratory), HOKLAS 016 (for medical laboratory) or HOKLAS
018 (for PTP).*

I confirm that our organisation will continue to abide by Chapters 4 to 8 of HKAS 002, HOKLAS
Supplementary Criteria No.33 or 34* irrespective of whether HKAS Executive agrees to adopt
Plan B.

Signed: _____

Date: _____

The legal name of the owner of the laboratory or proficiency testing provider which applies to adopt monitoring Plan B.

* Delete whichever is not applicable.

To be completed by the applicant	To be completed by the assessment team
Please tick the appropriate boxes and provide the information requested. (Clauses 1 - 4 relate to the pre-requisite for application.)	Please tick "Yes" box if there is sufficient information provided to confirm conformity with the criteria. Otherwise tick the "No" box.
1. The current reassessment and surveillance plan of our laboratory or PTP is <input type="checkbox"/> Plan A <input type="checkbox"/> Plan B <input type="checkbox"/> Plan C	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Please state whether your laboratory or PTP has been accredited by HKAS ¹ for the Test Categories included in the scope of accreditation (refer to the confirmed scope to be reassessed) for at least two years. <input type="checkbox"/> Yes _____ (please state the number of year since first accreditation for those Test Categories.) <input type="checkbox"/> No _____ _____ _____	<input type="checkbox"/> Yes <input type="checkbox"/> No Remark: _____ _____ _____ _____
3. There shall have been no drastic change to the organisation structure and ownership in the past 12 months. Please provide a brief history of changes to your organisational structure and ownership in the last 12 months. _____ _____ _____ _____	<input type="checkbox"/> Yes <input type="checkbox"/> No Remark: _____ _____ _____ _____
4. The management system shall be free from any major changes for at least 24 months. Please provide a brief history of changes to your management system in the last 24 months. _____ _____ _____ _____	<input type="checkbox"/> Yes <input type="checkbox"/> No Remark: _____ _____ _____ _____

To be completed by the applicant (Clauses 5 – 12 relate to requirements for this plan)	To be completed by the assessment team
<p>5. Please state whether your management system has been effectively implemented and is able to handle all routine operation through a combination of documented procedure and knowledgeable staff.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>For a “yes” reply, please list the evidence below and provide it together with this application form:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Remark:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
<p>6. Please state whether your management system has provisions in its procedures or documented contingency plan and the required resource to correctly handle all common failures.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>For a “yes” reply, please list the evidence below and provide it together with this application form:</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Remark:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
<p>7. Please state whether your turnover rate of key staff members was less than 15% per year in the preceding two years. If the number of key staff members is small such that 15% amounts to less than 1, 1 is allowed for the preceding two years provided that it does not constitute more than 35% turnover during that two-year period.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>For a “yes” reply, please list the evidence below and provide it together with this application form:</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Remark:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>

To be completed the applicant	To be completed by the assessment team
<p>8. Please state whether your laboratory or PTP has strong commitment to improvement.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>For a “yes” reply, please list the evidence of the strong commitment and briefly describe the preventive actions implemented since the establishment of the management system below and provide the details together with this application form:</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Remark:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
<p>9. Please provide the following accreditation history: If the number of accredited technical activities is small, i.e. 10% of the technical activities covered in the current reassessment amount to less than 1, please go to 9.2. The letters A, B, C, etc. are identification labels used for later calculations.</p> <p>9.1 For cases where 10% of the technical activities covered in the current reassessment amount to 1 or more.</p> <p><u>Last reassessment / assessment</u></p> <p>The number of critical or significant management system NCs _____ (A)</p> <p>The number of technical activities² covered _____ (B)</p> <p>The number of technical activities having 1 or more critical or significant NC _____ (C)</p> <p>The number of significant technical activity NCs _____ (D)</p> <p>The percentage of technical activities having 1 or more critical or significant NC³ $E = \frac{C}{B} =$ _____ %</p>	<p>Is A ≤ 2?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Is E ≤ 10%?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>

To be completed by the applicant

9.1 For cases where 10% of the technical activities covered in the current reassessment amount to 1 or more. (Cont'd)

Surveillance visits since the last reassessment / assessment

Surveillance visit since the last reassessment	1	2
Number of technical activities ² covered	F	G
Number of critical NCs	H	I
Number of significant management system NCs	J	K
Number of technical activity having 1 or more significant NC	L	M
Number of significant technical activity NCs	N	O
On average, the number of significant management system NCs per surveillance visit ⁴	$P = \frac{J + K}{\text{Number of surveillance visits}} = \underline{\hspace{2cm}}$	
On average, the percentage of technical activities having 1 or more significant NC per surveillance visit ⁵	$Q = \frac{L + M}{\text{Number of surviellance visits}} \times 100\% = \underline{\hspace{2cm}} \%$	

To be completed by the assessment team

Is $H = I = 0$?

- Yes
 No

Is $P \leq 1$?

- Yes
 No

Is $Q \leq 5\%$?

- Yes
 No

<u>To be completed by the applicant</u>	<u>To be completed by the assessment team</u>
<p>9.1 For cases where 10% of the technical activities covered in the current reassessment amount to 1 or more. (Cont'd)</p> <p><u>Current reassessment</u> The number of technical activities covered in the current reassessment _____ (R)</p>	<p>The number of critical NCs _____ (S)</p> <p>The number of significant management system NCs _____ (T)</p> <p>The number of technical activities found to have 1 or more significant NC _____ (U)</p> <p>The number of significant technical activity NCs _____ (V)</p> <p>Is S = T = 0?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Is $\frac{U}{R} \leq 10\%$?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p>9.2 For cases where 10% of the technical activities covered in the current reassessment amounts to less than 1.</p> <p><u>Last reassessment / assessment</u> The number of critical or significant management system NCs _____ (A)</p>	<p>Is A ≤ 2?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>

To be completed by applicants

9.2 For cases where 10% of the technical activities covered in the current reassessment amount s to less than 1. (Cont'd)

The number of technical activities² covered _____ (B)

The number of technical activities having 1 or more critical or significant NC _____ (C)

The number of significant technical activity NCs _____ (D)

Surveillance visits since the last reassessment / assessment

Surveillance visit since the last reassessment / assessment	1	2
Number of technical activities ² covered	F	G
Number of critical NCs	H	I
Number of significant management system NCs	J	K
Number of technical activity having 1 or more significant NC	L	M
Number of significant technical activity NCs	N	O
On average, the number of significant management system NCs per surveillance visit ⁴	$P = \frac{J + K}{\text{Number of surveillance visits}} = \underline{\hspace{2cm}}$	

To be completed by the assessment team

Is **H = I = 0**?

- Yes
 No

Is **P ≤ 1**?

- Yes
 No

To be completed by applicants

To be completed by the assessment team

9.2 For cases where 10% of the technical activities covered in the current reassessment amount s to less than 1. (Cont'd)

Current reassessment

The number of technical activities covered in the current reassessment _____ (R)

The number of critical NCs _____ (S)

The number of significant management system NCs _____ (T)

The number of technical activities found to have 1 or more significant NC _____ (U)

The number of significant technical activity NCs _____ (V)

Is **S = T = 0**?

Yes

No

Is **C + L + M + U** ≤ {**B** x 10% + **F** x 5% + **G** x 5% + **R** x 10% or 1, whichever is larger}?

Yes

No

Note: If there is only one surveillance visit conducted since the last reassessment, **G = M = 0**.

If more than 2 surveillance visits were conducted since the last reassessment, the table and the above formula should be extended according to the requirements of HKAS Supplementary Criteria No. 4.

To be completed by the applicant

To be completed by the assessment team

10. Please provide the following data.

a. The total number of proficiency results your laboratory or PTP has obtained since the last reassessment/assessment. _____ (W)

b. Out of these results, the number of satisfactory results. _____ (X)

$$\frac{X}{W} \times 100\% = \text{_____} \%$$

c. Please confirm that effective and timely corrective actions have been taken for all unsatisfactory or questionable results.

Yes No

For a "yes" reply, please list the evidence below and provide it together with this application form:

Is $\frac{X}{W} \times 100\% \geq 90\%$?

Yes

No

Remark:

Do findings of the current assessment support the claim?

Yes

No

Remark:

11. Are the corrective actions taken against critical or significant NCs identified since the last reassessment / assessment completed within the given periods of time (normally within 3 months of identification)?

Yes No

If yes, please list the evidence below and provide it together with this application form:

Yes

No

Remark:

<u>To be completed by the applicant</u>	<u>To be completed by the assessment team</u>
12. Number of recurring significant NCs found in the current reassessment.	<p>The number of recurring significant NC in the current reassessment _____ (Y)</p> <p>Is $\frac{Y}{D + N + O} \leq 20\%$?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
13. Number of minor NCs found in the current reassessment.	<p>Number of minor NCs found in the current reassessment⁶ _____ (Z)</p> <p>Is Z relatively small compared with the size of operation?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Remark:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>

	<u>To be completed by the assessment team</u>
<p>Notes:</p> <ol style="list-style-type: none"> 1. Please see Note 2 of HKAS Supplementary Criteria No. 4. 2. A technical activity is a test, calibration, or proficiency testing programme. A test or calibration includes all the steps necessary to obtain the given characteristics of the subject. The subject should be provided by the customer and the characteristics are those required by the customer. An intermediate step or a series of intermediate steps designed to prepare the test subject for subsequent steps is not itself a separate test or calibration. A product standard or piece of legislation may include many tests. Calibration of the same instrument for different ranges may be considered as different activities if different techniques are used. For a proficiency testing programme, it includes all the steps necessary to assess the performance of the participants. 3. The requirement is that not more than 10% of the technical activities have 1 or more critical or significant NC found in the last reassessment. 4. The requirement is that on average, the number of management system NCs shall be 1 or less per surveillance visit. 5. The requirement is that on average, not more than 5% of the technical activities shall have 1 or more significant NCs per surveillance visit. 6. Please see 4.2.1 e for HKAS Supplementary Criteria No. 4 Appendix II. 	<p>Conclusion:</p> <p>The laboratory or PTP</p> <p><input type="checkbox"/> Conform</p> <p><input type="checkbox"/> Do not conform</p> <p>with the requirements for Plan B.</p> <p>(Conformity is confirmed if answers to all the above questions are “yes”.)</p> <p>Adoption of Plan B is</p> <p><input type="checkbox"/> Recommended</p> <p><input type="checkbox"/> Not recommended</p> <p>Remark: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Name of assessment team leader: _____</p> <p>Signature: _____</p> <p>Date: _____</p>