



## Hong Kong Accreditation Scheme

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### HOKLAS 020

#### Application for Reassessment and Surveillance Plan C

Note:

1. Applications for adopting Plan C 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 C, irrespective of its current plan.
3. For accredited laboratories or PTPs applying to adopt Plan C, 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 C. For laboratories or PTPs intending to adopt Plan B, HOKLAS 019 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**

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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<sup>#</sup>)

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 C 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 C.

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

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

\* 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 - 3 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.
<p>1. By the time of the reassessment, have your laboratory been using Plan B or Plan C for at least 1 reassessment cycle with respect to the Test Categories included in the scope of accreditation (refer to the confirmed scope to be reassessed)?</p> <p><input type="checkbox"/> Yes                      <input type="checkbox"/> No</p> <p>For a "yes" reply, please state your current monitoring plan for those Test Categories:</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>2. There shall have been no major change to the management system, organisation structure, ownership, clientele and mix of accredited activities your laboratory performed in the past 24 months. Please provide a brief history of changes in such areas the last 24 months.</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>3. Following on from question 2, are there any expected major changes for those areas in the coming 24 months.</p> <p><input type="checkbox"/> Yes                      <input type="checkbox"/> No</p> <p>For a "yes" reply, please provide brief description for such changes:</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>

To be completed by the applicant (Clauses 4 – 15 relate to requirements for this plan)	To be completed by the assessment team
<p>4. 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>5. 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, and the majority of less 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>_____</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Remark:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
<p>6. Does your system value experience and lessons learnt?</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>	

To be completed the applicant	To be completed by the assessment team
<p>7. Following on from question 6, is your system effective in capturing experience and lessons learnt?</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>8. Please state whether your turnover rate of key staff members was less than 15% per year in the preceding three years. If the number of key staff members is small such that 15% amounts to less than 1, 1 is allowed for the preceding three years provided that it does not constitute more than 35% turnover during that three-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</p> <p><input type="checkbox"/> No</p> <p>Remark:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
<p>9. 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>

To be completed the applicant

To be completed by the assessment team

10. Has your organisation established a culture valuing quality and that its training and induction system is effective in inculcating such culture in new recruits?

- Yes                       No

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

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

11. 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 11.2.  
The letters A, B, C, etc. are identification labels used for later calculations.

11.1 For cases where 10% of the technical activities covered in the current reassessment amount to 1 or more.

The number of significant technical activity NCs found in the last reassessment \_\_\_\_\_ **(A)**

Surveillance visits since the last reassessment / assessment

Surveillance visit since the last reassessment	<b>1</b>	<b>2</b>	<b>3</b>
Number of technical activities <sup>2</sup> covered	<b>B</b>	<b>C</b>	<b>D</b>
Number of critical NCs	<b>E</b>	<b>F</b>	<b>G</b>
Number of significant management system NCs	<b>H</b>	<b>I</b>	<b>J</b>

Is **E = F = G = 0**?

- Yes  
 No

Is **H = I = J = 0**?

- Yes  
 No

To be completed by the applicant

11.1 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	<b>1</b>	<b>2</b>	<b>3</b>
Number of technical activity having 1 or more significant NC	<b>K</b>	<b>L</b>	<b>M</b>
Number of significant technical activity NCs	<b>N</b>	<b>O</b>	<b>P</b>
On average, the percentage of technical activities having 1 or more significant NC per surveillance visit <sup>3</sup>	$Q = \frac{K+L+M}{\text{Number of surveillance visits}} \times 100\% = \text{ \_\_\_\_\_\_ } \%$		

Current reassessment

The number of technical activities covered in the current reassessment \_\_\_\_\_ **(R)**

To be completed by the assessment team

Is **Q** ≤ 4%?

Yes

No

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  $\frac{U}{R} \leq 7\%$ ?

Yes

No

To be completed by the applicant

To be completed by the assessment team

11.2 For cases where 10% of the technical activities covered in the current reassessment amounts to less than 1.

The number of significant technical activity NCs found in the last reassessment \_\_\_\_\_ (A)

Surveillance visits since the last reassessment / assessment

Surveillance visit since the last reassessment / assessment	1	2	3
Number of technical activities <sup>2</sup> covered	B	C	D
Number of critical NCs	E	F	G
Number of significant management system NCs	H	I	J
Number of technical activity having 1 or more significant NC	K	L	M
Number of significant technical activity NCs	N	O	P

Is **E = F = G = 0**?

- Yes
- No

Is **H = I = J = 0**?

- Yes
- No

To be completed by applicants

To be completed by the assessment team

11.2 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  $K + L + M + U \leq \{B \times 4\% + C \times 4\% + D \times 4\% + R \times 7\% \text{ or } 1, \text{ whichever is larger}\}$ ?

Yes

No

Note: If there is only one surveillance visit conducted since the last reassessment,  $D = M = P$ .

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

12. Please provide the following data.

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

b. Out of these results, the number of satisfactory test 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:

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Is  $\frac{X}{W} \times 100\% \geq 93\%$

Yes

No

Remark:

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Do findings of the current assessment support the claim?

Yes

No

Remark:

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13. 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:

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Yes

No

Remark:

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<u>To be completed by the applicant</u>	<u>To be completed by the assessment team</u>
14. 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 <math>\frac{Y}{A+N+O+P} \leq 15\%</math> ?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
15. Number of minor NCs found in the current reassessment.	<p>Number of minor NCs found in the current reassessment<sup>4</sup> _____ (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"> <li>1. Please see Note 2 of HKAS Supplementary Criteria No. 4.</li> <li>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.</li> <li>3. The requirement is that on average, not more than 4% of the technical activities shall have 1 or more significant NCs per surveillance visit.</li> <li>4. Please see 4.2.1 f for HKAS Supplementary Criteria No. 4 Appendix III.</li> </ol>	<p><b>Conclusion:</b></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 C.</p> <p>(Conformity is confirmed if answers to all the above questions are “yes”.)</p> <p>Adoption of Plan C 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>