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# HKAS Supplementary Criteria No. 2

## Nonconformities and their grading

### 1. Introduction

- 1.1 This document defines nonconformities, their grading and the procedures that an applicant or accredited organisation shall follow to resolve them. It is applicable to all schemes, i.e. the Hong Kong Laboratory Accreditation Scheme (HOKLAS), the Hong Kong Certification Body Accreditation Scheme (HKCAS) and the Hong Kong Inspection Body Accreditation Scheme (HKIAS), except otherwise stated in the supplementary criteria documents of the concerned accreditation programme.
- 1.2 This document shall be used in conjunction with relevant accreditation regulations, HKAS policy, technical criteria and supplementary criteria documents.
- 1.3 Raising of nonconformities and assigning grades to them are the responsibility of HKAS assessment teams and HKAS accreditation officers. Decisions on accreditation, including whether to grant, continue, suspend or terminate accreditation are made by HKAS Executive.

### 2. Definition of nonconformity

- 2.1 Conformity is defined in clause 3.6.11 in ISO 9000: 2015 as 'fulfilment of a requirement'. Applying this definition to accreditation, a nonconformity is a non-fulfilment by an applicant or accredited organisation of relevant accreditation criteria as defined in HKAS 002 – including accreditation regulations, technical and management requirements and other accreditation conditions set by HKAS Executive.

### 3. Grades of nonconformity

Nonconformities are graded as *minor*, *significant* or *critical* depending on their effects

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on the validity of the accredited activity and the credibility of the accreditation scheme.

### 3.1 *Minor nonconformity*

A *minor nonconformity* is a nonconformity which has no serious adverse effect on the validity of the activity, its results or the competence of the organisation. It shall not be a deliberate violation of HKAS regulations for accreditation. In addition, it shall not seriously threaten the credibility of the accreditation scheme. All nonconformities which cannot be graded as *significant* (clause 3.2 below) nor *critical* (clause 3.3 below) are *minor nonconformities*. It should be noted that *minor nonconformities* have the propensity of developing into *significant nonconformities* and shall be investigated by the organisation immediately upon identification.

### 3.2 *Significant nonconformity*

A *significant nonconformity* is a nonconformity which has serious adverse effect on the validity of an activity, its results or the competence of the organisation or a deliberate violation of HKAS regulations for accreditation. Lack of commitment of the organisation to quality or conformity with accreditation criteria or existence of doubt on the integrity and impartiality of the organisation constitute *significant nonconformity*. The existence of a serious doubt on the technical validity of an activity or its results, as indicated by a series of related *minor nonconformities* is a *significant nonconformity*. Furthermore, persistence of a *minor nonconformity* for an extended period of time and without any plausible explanation may be a deliberate violation of HKAS regulations for accreditation, which is a *significant nonconformity*.

### 3.3 *Critical nonconformity*

A *critical nonconformity* is a nonconformity or a series of nonconformities which cast serious doubt on the validity of the conformity assessment result(s) or seriously threatens the credibility of the relevant accreditation scheme.

Gross lack of technical competence, persistent and intentional violation of HKAS regulations, gross lack of commitment of the organisation to quality or conformity with accreditation criteria, or existence of serious doubt on the integrity and impartiality of the organisation constitute *critical nonconformities*. A management system breakdown, as indicated by a series of *significant*

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nonconformities which seriously threaten the validity of all activities under the system, warrants a *critical* nonconformity.

Gross lack of competence may arise from lack of competent staff for critical activities, inappropriate environment for critical activities, lack of critical equipment, lack of critical traceability, totally invalid test, calibration or inspection method, total breakdown of the record or documentation system, lack of or totally ineffective quality assurance procedures or other causes.

#### **4. Raising of nonconformities and assigning of grades**

- 4.1 An HKAS assessment team or an HKAS accreditation officer may raise nonconformities during an assessment or other occasions for assessing an applicant or accredited organisation. They shall also determine the grades of the nonconformities in accordance with the grading definitions described in clause 3 above based on their observation and supporting evidence.
- 4.2 The party raising a nonconformity will record details of the relevant observations and the grade assigned to the nonconformity in an appropriate document. This document will be provided to the subject organisation as a formal notification that the nonconformity has been identified and the organisation is requested to take remedial actions. The document will include sufficient details of the observation to support the assigned grade. If the nonconformity raised is graded as *critical*, the rationale will also be stated in the document.
- 4.3 As a general rule, if a nonconformity is identified in an on-site assessment visit, even if the organisation has proposed or taken actions to correct it before the visit ends, it will still be raised. In such case, however, the considerations of the organisation in determining such actions, details of such actions, comments of the assessment team on their effectiveness and the chance of recurrence of the problem will also be recorded as part of the observation.

#### **5. Actions to be Taken to Resolve Nonconformity**

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- 5.1 The subject organisation is required to analyse the extent and cause of the nonconformity and determine the actions to be taken to resolve it within a timeframe specified by HKAS Executive.
- 5.2 The organisation, upon receipt of a notification of nonconformity, shall forthwith investigate the problem. It shall also afford HKAS Executive cooperation and provide all documents and other information as required for monitoring the implementation and evaluating the effectiveness of remedial actions. The organisation may have to inform relevant customers and recall any issued results/reports/certificates/validation and/or verification statements found to be doubtful in light of the outcomes of the investigation. The time allowed for completion of remedial actions and for reporting the same to HKAS Executive is given in 5.4 to 5.6.
- 5.3 The organisation may provide supplementary information to HKAS Executive for further consideration and review of a reported nonconformity. It shall inform HKAS Executive in writing of its views together with supporting evidence promptly upon receipt of the notification of such nonconformity. HKAS Executive will take into consideration of the subject organisation's view and the new supporting evidence to review if the reply adequately addresses the reported finding and where necessary, views from the assessment team will be sought. HKAS Executive will inform the organisation of the outcome of this review and the rationale in writing after thorough consideration and where necessary, seeking external advice on the acceptability of the actions taken or plans proposed.
- 5.4 For accredited activities
- a. The organisation shall, within one month from the date of the notification of nonconformity, report to HKAS Executive in writing the actions it has taken or plans to take to resolve the nonconformity. The organisation shall also provide all relevant information necessary for HKAS Executive to evaluate the acceptability of such actions.
  - b. If there is objective evidence indicating that an accredited organisation has failed to comply with or is incapable of complying with the accreditation criteria, the assessment team could raise one or more

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critical or significant nonconformity during a reassessment, HKAS Executive may suspend the relevant accredited activity(ies) if it considers necessary. In addition, if the accredited organisation fails to resolve the critical or significant nonconformities within the specified timeframe, HKAS Executive may suspend the relevant accredited activity(ies). HKAS Executive may arrange follow-up visits to verify the implementation and / or effectiveness of the remedial actions.

- c. For all *significant* nonconformities raised under HOKLAS and HKIAS, the organisation shall rectify them to the satisfaction of HKAS Executive within 3 months from the date of the notification of nonconformity. For HKCAS, the organisation shall rectify all significant nonconformities to the satisfaction of HKAS Executive within 2 months from the date of the notification of nonconformity. HKAS Executive may review the case and has the discretion to shorten this period as appropriate. The organisation shall also inform HKAS Executive the remedial actions in writing and provide all relevant information necessary for HKAS Executive to evaluate the effectiveness of such actions as soon as possible. HKAS Executive may suspend the relevant accreditation if the nonconformity cannot be resolved within that time period or the evidence provided cannot substantiate the implementation and/or effectiveness of the remedial actions.
- d. When one or more *critical* nonconformity has been raised, HKAS Executive will review the case and may suspend the accreditation of the relevant activities in accordance with the provisions in Chapter 6 of HKAS 002. When deliberating whether to suspend the accreditation, HKAS Executive will take into consideration all relevant factors, including but not limited to: the effect on the validity of the conformity assessment result(s), the causes of the nonconformity(ies); the damages that have been done; the probability that the damages can be contained by taking swift actions; and the effect of the nonconformity on the competence of the organisation, its conformity with accreditation criteria and its commitment to quality. If it is concluded that a suspension is not warranted, the organisation will be requested to resolve the nonconformity(ies), inform HKAS Executive of the same in writing and provide sufficient evidence that the nonconformity has been resolved within a time period specified by HKAS Executive, depending on its seriousness. If the organisation refuses to take remedial actions,

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does not inform HKAS Executive in writing that the nonconformity has been resolved, or fails to provide sufficient evidence that the nonconformity has been rectified within the specified time period, HKAS Executive may suspend the accreditation for the relevant activities.

An organisation which has its accreditation suspended shall follow the procedure detailed in Chapter 6 of HKAS 002.

- e. For *minor* nonconformities, the time allowed for rectification and reporting the same to HKAS Executive is given in 5.6.

#### 5.5 For activities for which accreditation is being sought

- a. For all *critical* and *significant* nonconformities, the organisation shall rectify them to the satisfaction of HKAS Executive within 6 months from the date of the notification of nonconformity. The organisation shall also inform HKAS Executive the remedial actions in writing and provide all relevant information necessary for HKAS Executive to evaluate the effectiveness of such actions. HKAS Executive may arrange on-site follow-up visits to verify the effectiveness of the remedial actions.
- b. For *minor* nonconformities, the time allowed for rectification and reporting the same to HKAS Executive is given in 5.6.
- c. HKAS Executive will not grant accreditation for an activity until all relevant *critical* and *significant* nonconformities have been addressed to its satisfaction.

#### 5.6 For *minor* nonconformities, the organisation shall rectify them within a period of time specified by HKAS Executive. The verification of the implementation and/or effectiveness of the remedial actions will normally be conducted in the next assessment for the relevant technical area. However, should subsequent investigation indicate that a *minor* nonconformity may be the sign of a *critical* or *significant* nonconformity, HKAS Executive may, at its discretion, arrange a follow-up visit or request the organisation to investigate and report to HKAS Executive on its findings with supporting evidence within a specified period of time.