First laboratory accredited by HKAS for medical testing

Press Release on 8 March 2005

A Department of Health laboratory had become the first to be accredited under the medical programme of the Hong Kong Laboratory Accreditation Scheme (HOKLAS) operated by the Hong Kong Accreditation Service (HKAS) under the Innovation and Technology Commission (ITC).

The HKAS today (March 8) presented an accreditation certificate to the Virology Division of the Public Health Laboratory Services Branch under the Centre for Health Protection, Department of Health, to give accreditation on its technical competence in clinical microbiology and infection under the HOKLAS medical testing test category.

HOKLAS is a voluntary scheme open to Hong Kong laboratories performing objective testing and calibration within the scope of the scheme and meet the HOKLAS criteria of competence. The area of medical testing was added to the scope of accreditation by HOKLAS in February, 2004. Laboratories accredited by HOKLAS are recognised as technically competent in this field by accreditation bodies in 40 economies worldwide under mutual recognition arrangements with HKAS.

"Public and private clinical pathology laboratories providing diagnostic testing services in five pathology disciplines – anatomical pathology, chemical pathology, clinical microbiology and infection, haematology and immunology – can seek accreditation under HOKLAS," an ITC spokesman said.

"Accreditation criteria are based on the new international standard for medical laboratories, ie, ISO 15189:2003 `Medical laboratories – Particular requirements for quality and competence’. Hong Kong is among the pioneers in adopting this new standard to accredit medical laboratories. Laboratories seeking accreditation undergo rigorous onsite assessments by experts in the medical testing field and they must participate in proficiency testing programmes and achieve satisfactory results."

"This accreditation was granted after rigorous on-site assessments carried out by overseas experts in accordance with the ISO 15189: 2003. HKAS congratulates the laboratory of their success in obtaining accreditation."

"Medical laboratory testing underpins the quality of medical services. The accreditation programme for medical laboratories contributes to the upgrading of the service standard of medical testing laboratories and will benefit the community."

"There is an increasing need for medical laboratories to demonstrate that they are up to international standards and accreditation is one way of meeting this need. The accreditation programme on medical testing provides an opportunity for medical laboratories to demonstrate their competence through a third party – HOKLAS," the spokesman said.
HOKLAS was launched in 1985 and currently has 122 laboratories accredited for a wide range of testing fields including electrical and electronic products, textiles and garments, toys and children’s products, food, calibration services, environmental, construction materials, chemical testing, Chinese medicine, physical and mechanical testing and medical testing.

Details of the accreditation programme on medical testing and relevant application documents are available on the HKAS website at www.info.gov.hk/itc/hkas. Laboratories interested in the programme may contact HKAS on 2829 4837. Applications can be submitted to the HKAS at 36/F Immigration Tower, 7 Gloucester Road, Wan Chai, Hong Kong.

Preparation for medical laboratory accreditation by HOKLAS

- Experience sharing from the Virology Division, Public Health Laboratory Services Branch, Centre for Health Protection, Department of Health, HKSAR Government

The following article is contributed by the Virology Division, Public Health Laboratory Services Branch, Centre for Health Protection, Department of Health, HKSAR Government. This laboratory is the first medical testing laboratory accredited by HKAS.

Much like testing in other laboratories, quality assurance is of utmost importance to medical testing laboratory to ensure output is consistent, reproducible, traceable and efficacious for patient management. In recent years, there is an increasing pressure for medical laboratories to be accredited to meet demands for conforming to or adopting international standards so as to ensure consistency of laboratory practice for training of personnel, satisfying service expectation as well as meeting the requirements of clinical trials and research.

Delivery of quality service has been our principal goal all along, and various measures and steps have been incorporated in multiple facets of our day-to-day work to ensure quality output. In fact, for many years, as World Health Organization National Laboratory for Polio, we have been following the WHO system and accredited through documentation of laboratory practice, output measurement and on site inspection. However, to be accredited by HOKLAS, it is necessary to review and compile all the quality components in accordance with the accreditation criteria.

In preparing for laboratory accreditation, the most important aspect was to let all staff understand accreditation is for the benefit of the service and patient care. For many years, senior staff were encouraged to attend HOKLAS courses on “Quality management in Laboratories” and “Internal audits”. Various in-house training courses and lectures on quality practice were also organized for all staff to familiarize them with the concepts and requirements of quality system.

Planning for accreditation began with a thorough study of the HOKLAS requirements. A framework of the quality system was subsequently devised to incorporate all the elements in the standard. The framework was then gradually built upon by incorporating procedures for each element, followed by their implementation. The first element to be tackled was document control. After the document control system had been implemented, other documents including management procedures such as organization of the quality system, internal auditing and continual improvement programme, and technical procedures such as standard operating procedures for various tests, specimen reception, reporting of test results and equipment maintenance programme were compiled to form the quality manual.

Having the quality manual in place was only the beginning. Implementation in accordance with what was documented, together with keeping of the necessary records, was continuous processes. In order to verify and ensure the effective implementation of the quality system, internal auditing and the continual improvement programme play important roles. Although in the year 2003, the new international standard for medical laboratories, ISO 15189, was issued, the basic requirements for the quality system were similar to ISO 17025, and only minor modifications to the system were necessary to fulfil the requirements.

Having gone through the accreditation process, our staff have acquired a renewed perspective on the importance of quality to the provision of the service. The accreditation of our laboratory by HOKLAS should be regarded as a bonus for assuring quality patient care, and as one of the milestones in our continuous journey on improving quality.
A bridging scheme for medical laboratories holding accreditation of other accreditation bodies was launched on 1 January 2005 for a period of two years to facilitate laboratories accredited either to ISO/IEC 17025 or other standards, to participate in the local scheme and to leverage their effort for attaining current accreditation. A briefing session on the bridging scheme was held on 3 December 2004 for these laboratories. A total of 25 participants from laboratories holding other accreditation attended the session. Enthusiastic responses were received from the participants.

The scheme aims to provide a means for medical laboratories to migrate from compliance with ISO/IEC 17025 or other accreditation standards in medical testing to ISO 15189. This is possible because ISO 15189 is based on ISO/IEC17025 but with specific requirements for medical laboratories such as laboratory safety, pre-examination procedures, post-examination procedures, determination of critical/alert intervals, turnaround times, etc. For other standards, many of their requirements are also similar to those of ISO 15189.

HKAS recognises this, and for those medical laboratories that have already been assessed by other accreditation bodies against their respective accreditation criteria, HKAS could focus on those elements which have not yet been covered. HKAS will take into consideration the assessment findings of other accreditation bodies and it is felt that a repetition of assessment on areas already assessed by other accreditation bodies may not be necessary. Similarly, since the quality system and operation procedures of these laboratories are more or less in conformity with ISO 15189, it is also envisaged that a much reduced effort is sufficient for these laboratories to upgrade their quality system and documentation to meet the requirements of HOKLAS. HKAS will determine the assessment time needed on a case-by-case basis. The duration of the on-site assessment for laboratories which are accredited by other accreditation bodies could be shorter and, as a consequence, the cost of assessment would correspondingly be reduced. To maintain the standard of accreditation, there must be evidence that all the requirements of ISO 15189 have been assessed, either through assessments by other accreditation bodies, or by HKAS in the initial assessment.

Medical laboratories accredited to ISO/IEC 17025 or other standards interested in this bridging scheme should apply to HKAS before 31 December 2006. Initial assessment must take place before their current accreditation expires.

Since the launching of the new accreditation service for gemstone testing in early 2005, four laboratories have been accredited for performing physical tests for identification of jadeite jade. They are:

1. Asian Gemmoligical Institute and Laboratory Limited (Registration No. HOKLAS 151)
2. China Gems Laboratory Limited (Registration No. HOKLAS 152)
3. Hong Kong Jade and Stone Laboratory (Registration No. HOKLAS 153)
4. SGS Hong Kong Limited (Registration No. HOKLAS 9)

Some other applications are being processed.

Accreditation of Gemstone Testing Laboratory

Gemstone testing is a test area under the “Physical and Mechanical” tests category. The tests covered include:

1. Shape and Cut Identification of Jadeite Jade
2. Measurement of Dimensions of Jadeite Jade
3. Measurement of Weight of Jadeite Jade
4. Identification of Transparency of Jadeite Jade
5. Identification of Colour of Jadeite Jade
6. Jadeite Jade Polariscope Examination
7. Determination of Refractive Index of Jadeite Jade
8. Determination of Specific Gravity of Jadeite Jade
9. Examination of Fluorescence of Jadeite Jade
10. Chelsea Colour Filter Examination
11. Jadeite Jade Spectroscopic Examination
12. Jadeite Jade Magnification Examination
13. Jadeite Jade Infrared Spectrum Examination

Tests are performed in accordance with “Standard Methods for
Mr. Chan delivering the opening speech.

Testing Jadeite Jade for Hong Kong” published by the Gemmological Association of Hong Kong (GAHK) earlier this year.

As part of the gemstone testing accreditation programme, reference jadeite jades for different degrees of transparency, ultraviolet fluorescence, chelsea colour filtering, polariscopic identification and refractive index, etc. have been established (See pictures of two examples of reference jadeite jades). A proficiency test (PT) on the 13 standard jadeite jade tests has been organised. The outcome of the PT indicated that most participating laboratories are performing satisfactorily and are able to produce accurate and reliable test results. (See picture of the eight artefacts jadeite jade used in the proficiency test)

Picture 1. An assessment of gemstone laboratory.

The accreditation of the gemstone testing laboratory for performing jadeite jade physical tests is the first stage of the gemstone testing accreditation programme. Extension of the programme to cover jadeite authenticity verification and diamond identification and grading and colour gemstones identification is being studied.

HKAS Assessor Seminar

On 8 March 2005, a record number of assessors and technical experts gathered at the YMCA Hotel for this year’s HKAS Assessor Seminar. We were also honoured to have Professor P C Ching, Chairman of the Accreditation Advisory Board (AAB) as well as other AAB members including Dr K F Wong, Dr T L Ting, JP, Dr Wilina Lim, JP, Professor H S Lau, Mr C Y So and Mr C C Tse attending this annual event.

Mr S S Chan, Executive Administrator, HKAS welcomed all attendees to the seminar and gave a talk on the recent development of HKAS. He highlighted that the number of accredited laboratories had increased steadily over the past 20 years and reached 121 at the end of last year. The number of accredited inspection bodies and certification bodies remained quite steady at 8 and 9 respectively in the past two years. Recently, HOKLAS has extended to cover medical testing and gemstone testing accreditation and, in the future, HKAS is considering extending HOKLAS to cover reference material producer and proficiency testing provider accreditation whilst HKCAS will extend to cover consumer product certification soon. Mr Chan further explained the challenges facing HKAS and the direction of HKAS development. He expressed his gratitude to the members of AAB, technical assessors and technical experts for their staunch support over the years.

Following Mr Chan’s talk was a presentation ceremony of the Certificate of Accreditation to the first accredited medical testing laboratory. The medical testing programme was launched in 2003 and the first medical testing laboratory that has successfully achieved accreditation is the Virology Division of the Public Health Laboratory Services Branch, Centre of Health Protection, Department of Health. Professor C P Ching, Chairman of AAB, presented the Certificate of Accreditation to Dr Wilina Lim, Head of the Public Health Laboratory Services Branch, Department of Health. Following is the speech of Professor Ching given at the presentation ceremony.

Today, apart from gathering together to share experience, I have the honour to present the accreditation certificate to the first medical laboratory accredited under the medical programme of HOKLAS. This laboratory is the Virology Division of the Public Health Laboratory Services Branch.
under the Centre of Health Protection, Department of Health of the Hong Kong SAR Government.

The HOKLAS medical programme was launched in February last year. The new international standard ISO 15189 is used as the accreditation criteria. This standard is gaining wide acceptance in many economies since its publication. Hong Kong is among the pioneers in adopting this standard.

Medical laboratory testing underpins the quality of medical services. The accreditation programme for medical laboratories contributes to the upgrading of the local health care system and will benefit the community. With the granting of accreditation to the first medical laboratory, we are moving one step closer to these goals. Through accreditation, laboratories can raise the standard of their service and demonstrate their competence. Accreditation also provides a convenient means for the public to identify competent service providers.

It is a great challenge to be the first laboratory to participate in a new programme. It takes much determination and management’s commitment, and effort from staff to set up a quality system that meets the requirement of ISO 15189 within just one year and to face the rigorous on-site assessment carried out by overseas experts. We invited Dr. Dominic Dwyer, a renowned virologist from the Westmead Hospital of Australia and Dr. Vered Agmon, the Head of the Israel Government Public Health Laboratory to conduct this first assessment. Both assessors were impressed with the quality system set up at the laboratory and the competence demonstrated by the laboratory staff during the assessment. The laboratory well deserves the accreditation and I would like to congratulate the laboratory for their success.

The theme of this year’s seminar is continual improvement of assessment process and we were delighted to have two very experienced technical assessors to share their experience with other assessors. The first speaker, Dr W M Kwok shared his experience in conducting assessments and ways to improve the assessment process. He outlined the general time allocated to each aspect of the assessment and provided valuable insights into the challenges faced by assessors and gave practical advice on how to deal with them.

The second speaker was Professor S L Ho. He is a very experienced technical assessor in electrical testing. He talked about the contributions of a technical assessor in preventing accidents, some of them were fatal ones, and improving the safety of the general public through assessments of laboratories to ensure that testing of electrical appliances was properly conducted. This is one of his main driving forces behind being a technical assessor for HKAS and pleaded other technical assessors to offer their support to HKAS. Professor Ho also shared his experience in assessment and pointed out that one of the most important elements to ensure proper testing was staff competence. To conclude his talk, he urged fellow assessors to continue update and upgrade their professional knowledge.
After the talks and presentation ceremony, assessors were divided into five groups according to their disciplines for more in-depth discussions on technical issues related specifically to their respective disciplines.

**Group for chemical and environmental testing**

**Twenty-one** assessors and technical experts attended this group which was led by Mr. W W Wong. We were also pleased to have Dr T L Ting, JP, Government Chemist and member of AAB joining this group. He provided us with valuable insights into many of the issues discussed. The discussion started with a presentation by Mr Wong on the feedback received from attendees of last year’s seminar and the approved amendments made to ISO/IEC 17025 which will be published. When this new edition is published, the criteria for laboratory accreditation will be revised accordingly and, since there are no major changes, it is expected that assessments will not be affected significantly. Assessors were briefed on the major amendments.

A system for grading of non-conformities was introduced in January last year. Recent feedback from laboratories indicated that they were general satisfied with this system. To refresh the basis of this grading system and to further harmonise the grading of non-conformities amongst assessors, examples were given to the participants for discussion. Assessors generally found the examples useful for clarifying some grey areas which they sometimes encountered during assessments.

Another area where assessors often need guidance is the minimum requirement for participation in proficiency testing programmes. Mr Wong highlighted the requirements given in HKAS 002, HOKLAS 003 and relevant HOKLAS Supplementary Criteria and explained that proficiency testing was a means to provide evidence on the competence of a laboratory to perform specific tests. As such, it is sometimes necessary to interpret the requirement in the context of the test concerned. For example, a successful participation in a proficiency testing programme on pH in drinking water may indicate a laboratory’s competence to perform the same test in sea water. On the contrary, successful participation in a proficiency testing programme on metals in drinking water may not indicate a laboratory’s competence to determine metals in sea water. Similarly, for multi-analyte tests, successful participation in some of the analytes may sometimes indicate competence of the laboratory to perform the other analytes, depending on the actual test procedure and the analytes concerned. Hence it is important to exercise professional judgement when interpreting the proficiency testing results, and there is no hard and fast rule that can be applied to this requirement. Mr Wong further explained some facts and myths of proficiency testing and stressed that participation in proficiency testing programme could not substitute routine internal quality control programmes.

Other topics discussed include estimation of measurement uncertainty and the feedback received from laboratories on assessments. Assessors and technical experts were pleased to note that some very encouraging feedback has been received.

**Group for chemical testing relating to construction materials**

The discussion was led by Dr. K. C. Pang, Senior Accreditation Officer. The ten attendees are assessors for air quality monitoring, asbestos testing or chemical analysis of construction materials. Assessors’ feedback on last year’s assessor seminar, including suggestions for HKAS future activities, was discussed. The nature of non-conformities identified during on-site laboratory assessments in 2004 was reviewed and summarised with breakdown figures for individual management and technical aspects. The group also discussed the HOKLAS requirements for appointments of lead assessors and technical experts, the roles and responsibilities for lead assessors acting as assessment team leaders and the basis for evaluation of performance of lead assessors and technical experts. Other relevant aspects, including reporting of findings, selection of documents for examination and tests to be witnessed as well as choice of check samples, were also covered.

In this group, two HKAS officers, Mr. K.W. Chen and Mr. W.L. Shum, discussed with 20 assessors. The group covered the approach to grading of non-conformities, issues relating to calibration and verification of equipment, and the implementation of the IAF/ILAC Guidance on the Application of ISO/IEC 17020.

A number of observations recorded in previous HOKLAS/HKIAS assessments were presented for discussion. Participants were invited to determine whether the observations were non-conformities, and if they were, to grade them accordingly. Assessors actively participated in the discussion and generally agreed to a harmonised approach to the grading of non-conformities. Assessors were reminded to record assessment findings in sufficient detail so that the assessed organisations could identify the root causes of the non-conformities and take appropriate corrective actions accordingly.

Assessors were briefed about the difference between calibration and verification of a measuring instrument. In general, calibration of an instrument is an operation to establish the relation between the values of quantity realised by the reference standard and the corresponding values indicated by the instrument under specified conditions while verification of an instrument is a confirmation through examination of the instrument and provision of objective evidence that it fulfils specified requirements. Calibration emphasizes measurement traceability whilst verification emphasizes functionality. Assessors were advised to refer to the ISO International Vocabulary of Basic and General Terms in Metrology (VIM) for further information.

With effect from 1 January 2005, all inspection bodies accredited under HKIAS have to comply with the IAF/ILAC Guidance on the Application of ISO/IEC 17020. Participants were briefed on the requirements of this document and the corresponding revisions to the accreditation criteria for consumer product inspection.
At the 14th APLAC MRA Council meeting, it was resolved that a workshop be held in Hong Kong to discuss issues related to a possible extension of the APLAC Mutual Recognition Arrangement (MRA) to cover accreditation of reference material producers (RMPs). The workshop was held on 11 and 12 March 2005 and was attended by 20 representatives from 14 APLAC accreditation bodies from 12 economies. A representative from InterAmerican Accreditation Cooperation (IAAC) also attended the workshop. The workshop was divided into four sessions, each dedicated to a specific topic and led by a facilitator. Three facilitators were invited. They were:

Ms. Ho giving an introduction on grading of non-conformities.

Designation of HOKLAS accredited laboratories as Conformity Assessment Bodies under APEC Tel MRA

Office of the Telecommunications Authority (OFTA) has recently published a revised Information Note “Asia-Pacific Economic Cooperation (APEC) Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment (APEC Tel MRA)” on its website. The purpose of the Information Note is to update the general public and interested parties with the fact that Hong Kong has entered into arrangement with the US for the implementation of Phase I (mutual recognition of test reports) and Phase II (mutual recognition of equipment certification) procedures of APEC Tel MRA since April 2005. Before that, Hong Kong had already made similar arrangements with Australia, Canada, Singapore and Chinese Taipei for the implementation of Phase I Procedures. A testing laboratory which is accredited under HOKLAS for specific telecommunications equipment tests or EMC tests in the test category of “Electrical and Electronic Products” may be designated by OFTA as conformity assessment bodies (CAB’s) under APEC Tel MRA. So far, OFTA has designated some local testing laboratories as CAB’s and the test reports produced by them will be accepted by the corresponding APEC economies as those produced by CAB’s in their economies. Any testing laboratory or certification body who is interested in becoming CAB may access OFTA’s website http://www.ofta.gov.hk/en/tec/main.html for more details.

APLAC Workshop on Reference Material Producer Accreditation

There were 55 participants in this group. They include pathologists, scientific officers and a number of experienced medical technologists from both the public and the private sectors, and their expertise covered different medical laboratory disciplines, viz anatomical pathology, chemical pathology, microbiology and haematology.

The discussion focussed on the grading of non-conformities for medical testing. It began with a brief introduction by Ms. Bella Ho on the grading of non-conformities, and then followed by an exercise on grading of 22 observations in different medical testing disciplines. Each of these observations and the grading assigned were subsequently discussed with enthusiasm.

This exercise served to illustrate that, although assessors are experts in their own discipline, subjective opinion may affect the grade assigned to a non-conformity. The discussion helped to achieve consistent application of the grading system. Participants also agreed that the grading of a particular observation might depend on other factors as well as on the actual situation of the laboratory at the time of assessment. All participants enjoyed this exchange of ideas and many expressed that they would like to have more such experience sharing sessions in future.
The fifth HOKLAS-HKIAS liaison meeting was held on 16 December 2004. Eight representatives from accredited laboratories or inspection bodies attended the meeting. Mr S. S. Chan, Mr. W. W. Wong and Mr. C. K. Cheung represented HKAS at the meeting. Following are some of the issues discussed.

1. HKAS Executive has recently conducted a review of the grading system launched on 26 January last year for non-conformities identified in assessments of laboratories and inspection bodies. The review indicates that, not only has the system been proved useful according to the feedback from the assessors and the organisations assessed, both the granting and reaffirmation of accreditation have also been expedited. The average time taken for granting accreditation is substantially reduced from 96 days to 56 days for initial application and from 129 days to 79 days for extension, while that for reaffirmation is also cut by 4 days, from 86 days to 82 days. Based on these favourable findings, the Accreditation Advisory Board has endorsed, at its seventh meeting, the continuation of the grading system for future assessments of laboratories and inspection bodies. Laboratory and inspection body representatives to the liaison meeting were invited to give their views and suggestions to HKAS for improving this system.

2. A revised procedure for dealing with changes in name and ownership of an accredited organisation was implemented. In gist, accreditation will be granted under the name of the legal entity which owns the business or firm that performs the activities accredited. For the name change of an accredited organisation, accreditation may be continued provided that there are no other changes which may affect the conformity of the organisation with the accreditation criteria. As for any changes in ownership of an accredited organisation which is not, by itself, a legal entity, the accreditation granted under the name of the original owner will be terminated when the change takes effect. If the new owner wishes to maintain accreditation under the new ownership, it needs to apply anew to HKAS Executive.

3. The revised system for submission of information and documents to HKAS Executive and technical assessors was implemented on 1 December 2004. Accredited laboratories and inspection bodies were briefed on this system on 15 November 2004. Representatives to the liaison meeting were invited to provide HKAS Executive with their views and feedback on the revised system.

4. Laboratory representatives were informed that the second edition of ISO/IEC 17025 would be published very soon. However, there will be no major change apart from, for example, the requirement for continual improvement. It is anticipated that most accredited laboratories would not have major problems complying with the new standard. Similarly, inspection body representatives were informed that the IAF/ILAC Guidance on application of ISO/IEC 17020 had been published and could be obtained from the IAF website. The implementation date for this guidance document was January 2005. This guidance is mandatory to accredited inspection bodies. A major change is that inspection body should witness every inspector at least once during the normal accreditation cycle in performing every field of inspection he/she has been authorised by the inspection body.

5. To understand their need better, HKAS Executive is considering improving the liaison with representatives of end users of laboratory and inspection body services. Laboratory and inspection body representatives were invited to identify and suggest to HKAS Executive any of their major clients who might wish to take part in the liaison.

6. The current accreditation regulations allow the reinstatement of a suspension immediately upon confirmation that the cause of the suspension has been rectified. This may lead to an abuse of the system thereby an accredited organisation voluntarily suspends its accreditation upon identification of a critical non-conformity, but ask for re-instatement immediately or shortly thereafter. This issue was discussed. Some representatives of accredited organisations agreed that there should be a minimum period for suspension but others expressed reservations about it.

Meeting with Certification Bodies

After attending the International Accreditation Forum (IAF) Technical Committee meeting in February 2005 in Taiwan, China, Mr. Tommy Fung, Senior Accreditation Officer, HKAS, held a meeting with representatives from the 9 HKCAS
The second edition of ISO/IEC 17025 was published on 15 May 2005. According to an ILAC resolution, accredited laboratories have to implement this new edition two years after the publication of the standard. HKAS is working on a transitional plan which will be announced soon. In the meantime, accredited laboratories are advised to study the new standard carefully and prepare to implement the necessary changes to their management system.

APLAC 2004 General Assembly and Meetings

The annual Asia Pacific Laboratory Accreditation Cooperation (APLAC) General Assembly and other meetings including Board of Management meeting, Training Committee meeting, Proficiency Testing Committee meeting, Public Information Committee meeting and Mutual Recognition Arrangement Council meeting, were held in Hanoi, Vietnam during the period 5 to 10 December 2004. Mr S. S. Chan and Mr W. W. Wong attended the meetings. Some points worth noting are:

1. The Proficiency Testing Committee approved HKAS, in collaboration with the Government Laboratory, Hong Kong, to organise a proficiency testing programme on pesticide residues in herbal medicine under the auspices of APLAC in 2005.

2. The Mutual Recognition Arrangement (MRA) signatory status of CNAL, China, KAN, Indonesia, and BoA, Vietnam was extended to include inspection.

3. Mr Tony Russell of NATA, Australia was elected as Chair of APLAC whilst Mr S. S. Chan, Executive Administrator of HKAS, was elected as Chair of the MRA Council. Mr Yoshinobu Uematsu of IAJapan was elected as Chair of the Technical Committee.

APLAC ISO/IEC 17011 Workshop and MRA Council Meeting

An APLAC lead evaluator and ISO/IEC 17011 workshop was held on 22-24 April 2005 in Tokyo, Japan. A total of 43 participants from 31 accreditation bodies and 22 economies attended this workshop. The need of this workshop arose from the publication of ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies in September 2004. Signatories to the APLAC MRA are required to comply with the requirements of this standard by 31 December 2005. The purpose of this workshop was two-fold. Firstly, current APLAC lead evaluators need to be updated on the requirements of this standard. Secondly, accreditation bodies need to be aware of the new requirements, and their applications, in order to facilitate transition to this new standard.

The workshop was coordinated by Mr Peter Unger of A2LA, who was assisted by three moderators, viz., Mr S. S. Chan of HKAS, Mr Barry Ashcroft of IANZ and Dr Pannada Silva of DMSc. Each requirement of ISO/IEC 17011 was discussed with special emphasis placed on the differences between the old standards (ISO/IEC Guide 58 and ISO/IEC TR 17010) and this new standard. Vivid discussions were held and interpretations of the requirements were clarified. Several key differences between the existing and the new standards were identified. Mr W. W. Wong, HKAS, attended this workshop.

Immediately following the workshop was a two-day APLAC MRA Council meeting. Main decisions and issues discussed include:

1. The MRA status of International Accreditation Service Inc. (IAS) of USA has been extended to cover calibration.

2. It was decided that the APLAC MRA be extended to cover accreditation of reference material producers.

3. All signatories to the APLAC MRA are required to comply with ISO/IEC 17011 by 31 December 2005. A lead evaluator will be appointed to evaluate the information provided by accreditation bodies on their conformity with ISO/IEC 17011. A MRA Council meeting will be held in mid-2006 to hear the reports from the lead evaluators.

4. The Council discussed the desirability of separating medical testing into a distinct entry in the APLAC MRA. The Working Group for studying effectiveness of the APLAC MRA has been asked to study the issue and report to the Council at its November meeting.
ILAC Laboratory Survey on Conversion to ISO/IEC 17025:1999

Following is an extract of a survey on the conversion from ISO/IEC Guide 25:1990 to ISO/IEC 17025:1999 by accredited laboratories conducted by the ILAC Laboratory Committee in 2003. In this survey, some very interesting information was identified, and in view of the publication of the second edition of ISO/IEC 17025:2005, the results of the survey could serve as valuable experience on which the conversion to the second edition of ISO/IEC 17025 could be based. A full report is available from the website of ILAC at http://www.ilac.org.

ISO/IEC 17025:1999 was published after extensive consultation with stakeholders. There were quite a number of “new” and “revised” requirements with which accredited laboratories need to comply. The transition period ended on 31 December 2002. In 2003, the ILAC Laboratory Committee decided that a survey should be undertaken to test the extent to which there were on-going problems faced by laboratories in relation to the conversion. More than 2000 responses from 51 economies were received representing a return rate of over 10 per cent. Considering the extent of the changes in the laboratory accreditation standard, it is remarkable that the laboratory community generally considered that the transition was smooth.

The issue that was ranked as the most problematic by laboratories was the estimation of measurement uncertainty. 64% of the respondents indicated that they had had issues or were still having issues with estimation of measurement uncertainty. HKAS was aware of this since the publication of the standard in 1999 and has identified that estimation of measurement uncertainty, particularly for testing, as one of the areas where training was most needed by laboratories as well as technical assessors. Accordingly, HKAS has organised training courses dedicated to each specified field, e.g. chemical analysis, construction material testing, microbiological testing, etc., since 2001. A training course dedicated to technical assessors in chemical analysis was held in June 2001. A one-day advanced workshop course on estimation of measurement uncertainty in chemical testing was organised since 2002. These training courses are being organised on an on-going basis. It should also be noted that training courses on estimation of measurement uncertainty in calibration have been organised by HKAS for many years.

HKAS also hosted a 3-day APLAC workshop on measurement uncertainty in testing, the outcomes of which have resulted in the publication of an APLAC Guidance document on estimation of measurement uncertainty in testing – APLAC TC005. This guidance document is the result of the hard work of 47 experts from 10 economies in the Asia Pacific Region. This document is available from the website of APLAC at http://www.aplac.org.

When asked if they agreed with the statement – “the key staff in our laboratory know enough about ISO/IEC 17025 to maintain our accreditation”, the majority of laboratories (96 per cent) agreed or strongly agreed. In the local context, HOKLAS 003 Technical Criteria for Laboratory Accreditation was revised and published in July 2000 to keep it in line with ISO/IEC 17025:1999. In order to familiarise assessors as well as laboratories with the new requirements, a one-day seminar was held on 15 September 2000. 252 technical assessors and laboratory representatives attended this seminar. Each clause of the new standard was discussed and new requirements were highlighted and the policy for estimation of measurement uncertainty was explained in detail. This is probably one of the key factors for the successful conversion to ISO/IEC 17025:1999 in Hong Kong.

In another question, respondents were asked to rate the amount and quality of the information on issues related to ISO/IEC 17025:1999 available from a range of sources (accreditation bodies, laboratory associations, governments, professional bodies, standards bodies, ILAC, regional bodies and academic bodies.). We are glad to note that laboratory managers are generally very happy with the help they received from accreditation bodies. To assist accredited laboratories to convert to ISO/IEC 17025, a gap-analysis was performed for all assessments conducted after the publication of HOKLAS 003 until end of 2001. Non-conformities against ISO/IEC 17025:1999 were raised as recommendations and laboratories were required to resolve these by the end of 2001, if their accreditation was to be maintained after that date. All accredited laboratories have been converted to the new standard on or before the transition period stipulated by ILAC.

The survey revealed that two issues that laboratories need most information or training were measurement uncertainty and method validation. Training courses on these topics were organised last year in October by HKAS. Similar courses will also be organised this year.

Laboratory managers were also asked to express a view on whether the new laboratory accreditation standard had enhanced the distinction between laboratory accreditation and certification. A majority (67 per cent) thought that it had, which suggests that the distinction is important to laboratory managers. Interested readers may refer to a communique prepared by the IAF-ILAC-ISO/CASCO Joint Working Group on Image and Integrity of Conformity Assessment to clarify the key distinctions between the two different types of recognition provided separately by accreditation bodies and certification bodies. A reproduction of this communique was published in issue number 33 of HKAS News, which is available from the website of HKAS at http://www.info.gov.hk/itc/hkas.

Another key finding of the survey was that most laboratories are happy to be accredited. Those that are not so pleased tend to complain about the cost and inconvenience of the standard and the accreditation process. Similarly, a strong majorities of respondents considered that laboratory accreditation is a good investment and that proficiency testing and other interlaboratory comparison provide good value.
### ILAC and IAF General Assembly and Meetings

The International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) General Assemblies and conferences were held in Cape Town, South Africa in October 2004. This was an annual event organised jointly by ILAC and IAF. It consisted of a series of meetings, some of them were joint meetings of ILAC and IAF, and included, for example, the ILAC Accreditation Policy Committee meeting, the ILAC Arrangement Committee meeting, the ILAC General Assembly, the IAF Technical Committee meeting, the Joint ILAC-IAF Inspection Committee meeting, IAF General Assembly, the joint ILAC-IAF General Assembly, etc. Matters relating to accreditation of laboratories, certification bodies and inspection bodies were discussed. Mr. W. W. Wong and Mr Tommy Fung of HKAS attended the conferences and meetings. Some of the key outcomes of this event include:

1. Mr. Tommy Fung represented HKAS in signing the IAF Quality Management System Multilateral Mutual Recognition (MLA) on 9 October 2004.

   Signatories to the MLA recognise the certificates issued by certification bodies accredited by the other signatories to the MLA as equivalent to those issued by certification bodies accredited by themselves.

2. The following new signatories joined the ILAC MRA:
   i. Department of Standards Malaysia (DSM) – extension to calibration
   ii. National Accreditation Body of Indonesia (KAN) – extension to calibration
   iii. Slovenian Accreditation (SA) – testing and calibration
   iv. Hellenic Accreditation Council (ESYD) – testing and calibration
   v. Romanian Accreditation Association (RENAR) – testing

   Iran Accreditation System (IAS), Pakistan National Accreditation Council (PNAC), Assured Calibration and Laboratory Accreditation Select Services (ACLASS) of USA, and Egyptian Accreditation Council (EGAC) also joined ILAC as Associates. Associates are accreditation body members of ILAC which are not signatories to the MRA.

3. The ILAC General Assembly resolved that assessing the technical competence of bodies producing reference materials with assigned values was accreditation of conformity assessment activity and that accreditation in this field would be conducted against harmonised criteria based on ISO Guide 34 and ISO/IEC 17025 in combination.

4. In anticipation of the publication of the second edition of ISO/IEC 17025, it was resolved that the transition period for the implementation should be two years from the date of publication of the standard.

5. It was noted that the significance of the ILAC MRA in facilitating trade was very often overlooked or underestimated by governments. In view of this, a task force was established to study the economic impact of the MRA.

6. To further enhance ILAC as the platform for competence assessment activities, it was resolved that ILAC should promote and foster the development of relationships with other competence assessment bodies like World Anti-doping Agency (WADA), Organisation for Economic Cooperation and Development (OECD), International Electrotechnical Commission (IEC), etc.

7. The ILAC General Assembly agreed to use the ILAC-IAF Guidance document on ISO/IEC 17020 from 1 January 2005.

### ILAC ARC Meeting

The first International Laboratory Accreditation Cooperation (ILAC) Arrangement Committee (ARC) was held on 3 and 4 March 2005 in Paris, France. Mr. W. W. Wong represented Hong Kong Accreditation Service to attend the meeting. The ILAC ARC replaces the Accreditation Policy Committee (APC) and its remit is to consider and formulate policies on issues related to the development and maintenance of procedures and requirements for the implementation of the multilateral mutual recognition arrangement (MLMRA), and the development of new dimensions and extensions to the arrangement.

Some of the key issues discussed are:

1. To improve the profile of ILAC to national and international authorities and to enhance the acceptance of ILAC MLMRA by them, a working group was formed. The countries/region that this group should focus on are USA, Japan and Europe. This work may enhance the acceptance of test reports from HKAS accredited laboratories by regulatory authorities in these economies, which are the main trading partners of Hong Kong.

2. Investigating the economic impact of the ILAC MLMRA was identified as a priority area. The Chief Executive of
A meeting of the IAF-ILAC-ISO Joint Working Group (JWG) took place on 7 November 2004 in Amsterdam, the Netherlands. The JWG is a high level collaborative group amongst the following organizations:

- International Accreditation Forum (IAF);
- International Laboratory Accreditation Cooperation (ILAC); and
- International Organization for Standardization (ISO).

The JWG was established after the signing of the IAF-ILAC-ISO Memorandum of Understanding (MoU) Concerning Cooperation and Mutual Assistance on Accreditation as Part of Conformity Assessment in March 2004, and its purpose is to act as a clearinghouse for the identification, preliminary analysis, coordination, and division of responsibilities for dealing with issues surrounding conformity assessment policy, standards development and practice as they relate to accreditation.

At the second meeting a number of items were discussed as follows:

**ISO/IEC 17011 Transition period**

The JWG noted that the IAF and ILAC memberships had at their annual General Assemblies in October 2004 resolved that all accreditation body members should meet the requirements of the new ISO/IEC 17011:2004, Conformity assessment – General requirements for operation and recognition, General requirements for assessment and accreditation of certification/registration bodies; and ISO/IEC TR 17010:1998, General requirements for bodies providing accreditation of inspection bodies.

ISO 14001 Transition period

A new edition of the standard that was published on 15 November 2004 has replaced ISO 14001:1996. The JWG noted that the IAF had resolved at their General Assembly in October 2004 to establish a transition period for certificates from accredited certification bodies. The transition period has been set at 18 months to allow the migration of certification based on the requirements of ISO 14001:1996 to being based on the requirements of ISO 14001:2004.

After this 18-month transition period expires the only valid ISO 14001 certificates from accredited certification bodies will be those meeting the requirements of ISO 14001:2004.

Requirements for third party auditors

It was agreed that an IAF-ISO Task Force should be established to analyse the need within the conformity assessment community for requirements that would cover the competence of auditors of management systems. This Task Force will bring together the necessary experts in both organizations to assess this issue. Once established, the Task Force is to undertake its work and recommend further action (if necessary) to the next meeting of the JWG scheduled for June 2005.

In the interim the new IAF Technical Committee Working Group to establish IAF guidance on the application of ISO 19011:2002 will continue with its preliminary work.

International Accreditation Japan (IAJapan) was appointed to convene a working group on this project.

4. A guidance document is being written for the implementation of ISO 15189. ISO 15189 is the basis of HOKLAS 015 which is the accreditation criteria for the medical testing laboratories. In view of its importance, a mirror group was formed under ARC, and Ms Bella Ho of HKAS was a member of this group.

5. A requirement on the minimum participation in proficiency testing programmes has been approved by ILAC. The date of publication of this requirement is February 2005. The implementation date of this requirement was agreed to be 1 January 2006. A resolution to this effect will be put forward to the ILAC General Assembly in September 2005. This will not affect HOKLAS accredited laboratories as the HOKLAS existing requirement already meets the new ILAC requirement.

3. A meeting amongst ISO, IAF and ILAC was held in November last year to discuss issue of including a reference to ISO 9001 on accreditation certificates. The following statement was suggested – "This laboratory is accredited in accordance with ISO/IEC 17025:2005. Accreditation demonstrates technical competence for a defined scope and operation of an international recognised quality management system (see joint ISO-ILAC-IAF Communiqué reference dated xxx 2005). The joint communiqué states that the management system requirements in ISO/IEC 17025 meet the principles of ISO 9001 and are aligned with its pertinent requirements. Once the communiqué is signed by ISO, ILAC and IAF, the ILAC accreditation bodies, including HKAS, may begin to use the statement on the accreditation certificates."
Survey on management system certificates and on laboratory accreditation

The annual survey by ISO of ISO 9001 and ISO 14001 certificates from accredited certification bodies was discussed. ISO invited the IAF to assist in the design and implementation of the survey in the future. Separately, ILAC agreed to work with ISO to establish an annual ISO Survey on the global numbers, sectors and places of laboratory accreditations to ISO/IEC 17025 and ISO 15189.

Process for handling of complaints about conformity assessment practice

Discussions also took place on the most effective way for the parties to respond to complaints about conformity assessment practice, whether the complaints were in relation to non-accredited or accredited conformity assessment activities. A procedure will be confirmed in due course amongst the parties.

IAF cross frontier policy

The following is an excerpt from a press release of IAF on cross frontier policy published in October 2004.

The International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) Management Committee (MC) adopted a number of practices to enhance implementation of IAF Guidance on Cross Frontier Accreditation during its Plenary Meeting held on October 8, 2004, in Cape Town, South Africa. These include sharing best practices, regular assessments of effective implementation, and maintenance of up-to-date information on critical locations.

The process was initiated in September 2003 when IAF’s General Assembly approved the IAF Guidance on Cross Frontier Accreditation, the main purpose of which is to facilitate cooperation among Accreditation Bodies (ABs) in auditing critical locations and enhance the networking and capability of ABs worldwide. Results of a June 2004 survey on MLA signatories showed that all signatories (except where not applicable such as operating only locally) had a plan in place to conform to the requirements and are implementing the policy and related requirements.

Subsequently, the MLA MC chartered a Cross Frontier Practices Group (CFPG) to monitor implementation and report suggestions for implementation. Results of a second survey conducted from the perspective of the host country substantiated the findings of the first survey and helped identify critical locations. Responding ABs indicated that both multilateral and bilateral arrangements were already in place; in addition, ABs have arrangements to exchange reports, work with each another as subcontractors, and act as observers and interpreters.

The CFPG made these recommendations to the MLA MC:

- Cross frontier best practices should be gather and posted on IAF’s Web site.
- The MLA MC should assess implementation of the Cross Frontier Policy at each peer evaluation, focusing on the AB’s plan, proper allocation of resources within the organization, arrangements with other ABs, and evidence of the implementation of the plan.
- As a control, ABs should require their accredited Certification Bodies to periodically supply a list of all critical offices. The host AB should advise the local ABs sufficiently in advance of those offices and plan for audits using a method that meets the requirements of the Cross Frontier Policy.
- A seven-step process for implementation should be used:
  1) Outline the plan.
  2) Identify the commitment to the plan.
  3) Identify the resources necessary to fulfill the plan.
  4) Assure that all needed arrangements are in place.
  5) Put in place the necessary operating plans, including internal system and resources.
  6) Begin to implement the system.
  7) Apply the principles of continual improvement.

These seven steps must also be applied to other ABs with which the implementing AB has arrangements. The overall plan should result in the required frequency and integrity of audits of all critical locations.

Accreditation Update

New Accreditation Granted

Seven new laboratories and two new inspection bodies have been granted accreditation since the last issue of HKAS News. Details are given below.

HOKLAS

Asia Gemmological Institute and Laboratory Limited (HOKLAS Registration No. 151) is the first HOKLAS accredited laboratory in Hong Kong for physical tests of gemstones under the test category of “Physical and Mechanical Testing”. The laboratory provides testing service to the public.

Pharmtech (Hong Kong) Limited – Quality Control Laboratory (HOKLAS Registration No. 154) has been accredited for pharmaceutical products testing under the test category of “Chemical Testing”. The laboratory provides testing service to the public.

China Gems Laboratory Limited (HOKLAS Registration No. 152) and Hong Kong Jade & Stone Laboratory (Registration No. HOKLAS 153) have been accredited for gemstone testing under the test category of “Physical and Mechanical Testing”. The laboratories provide testing service to the public.

Pharmtech (Hong Kong) Limited – Quality Control Laboratory (HOKLAS Registration No. 154) has been accredited for pharmaceutical products testing under the test category of “Chemical Testing”. The laboratory provides testing service to the public.
Castco Testing Centre (Shenzhen) Limited (HOKLAS Registration No. 155) has been accredited for physical tests of aggregates and concrete under the test category of “Construction Materials”. It provides testing service to the public.

The Virology Division, Public Health Laboratory Services Branch, Centre for Health Protection, Department of Health (HOKLAS Registration No. 801P) is the first laboratory accredited by HKAS under the Medical Testing Test Category. This laboratory is directed by a pathologist. The scope of accreditation covers examinations in the discipline of clinical microbiology and infection. It provides services to public and private hospitals and clinics.

Diagnostix Pathology Laboratories Ltd. (HOKLAS Registration No. 802P) has been accredited for examinations in the discipline of anatomical pathology under the test category of “Medical Testing”. The laboratory is directed by a pathologist and provides services to private hospitals and clinics.

HKIAS

Asia Pacific Inspection Limited (HKIAS Registration No. 009) is accredited for the pre-shipment inspection for kitchenware under the inspection field of “Consumer Product” and provides inspection service to the public.

ETS-Testconsult Limited (HKIAS Registration No. 010) is accredited for welding inspection under the inspection field of “Construction products”. The inspection body provides service in inspection/approval of welding procedures and inspection/approval of welder testing to the public.

Accreditation Suspended and Reinstated

ETS-Testconsult Limited (HKIAS Registration No. 022) voluntarily suspended all HOKLAS accredited physical and site tests for concrete under the test category of “Construction Materials” effective 24 December 2004. Accreditation for all the suspended tests was reinstated on 13 April 2005.

The Hong Kong Standards and Testing Centre Ltd. (HOKLAS Registration No. 003) has voluntarily suspended all HOKLAS accredited EMC tests under the test category of “Electrical and Electronic Products” effective 29 March 2005. Stanger Asia Limited (HOKLAS Registration No. 021) has voluntarily suspended all HOKLAS accredited cooking benches and sink units tests under the test category of “Construction Materials” effective 1 November 2004.

Change of Legal Status

Bureau Veritas Consumer Products Services (Hong Kong) Limited - Kwai Chung Office (HOKLAS Registration No. 053) voluntarily terminated the accreditation for all tests in all test categories effective 1 December 2004. The accreditation for some tests has been granted to Bureau Veritas Hong Kong Limited – Kwai Chung Office under the same Registration Number.

Bureau Veritas Consumer Products Services (Hong Kong) Limited – Kowloon Bay Office (HOKLAS Registration No. 058) voluntarily terminated the accreditation for all tests in all test categories effective from 1 December 2004. The accreditation for some tests has been granted to Bureau Veritas Hong Kong Limited – Kowloon Bay Office under the same Registration Number.

In due course.

The accreditation for all tests under the test category of “Chemical Testing” of the Macau Jockey Club – Racing Laboratory (HOKLAS Registration No. 107) was voluntarily terminated with effect from 30 January 2005. The accreditation for the same tests has been granted to Macao University of Science & Technology Foundation – Racing Laboratory under the same Registration Number.

Accreditation Terminated

QA Testing Centre Limited (HOKLAS Registration No. 020) has voluntarily terminated the accreditation for all tests effective 1 December 2004.

The Hong Kong and China Gas Co. Ltd. – Tai Po Laboratory (HOKLAS Registration No. 117) has voluntarily terminated the accreditation for all tests effective 1 April 2005.

The Chinese University of Hong Kong – Advanced Surface and Materials Analysis Centre (HOKLAS Registration No. 132) has voluntarily terminated the accreditation for all tests effective 8 April 2005.

Proficiency Testing Update

Construction Materials

An update on the proficiency testing programme organised by HKAS in 2005 is given below:

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Toys and Children’s Products

The interim report for the APLAC T039 – Toy Safety Proficiency Testing Programme has been issued to participating laboratories. The preparation of the final report by the Government Laboratory is underway.

Chinese Medicine

Samples for the APLAC T043 – Herbal Medicine Proficiency Testing Programme have been distributed to participating laboratories and some participants have already returned their test results. This programme is jointly organised by HKAS and Government Laboratory under the auspices of APLAC. Some delay of the

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programme is expected as problems in delivering samples to some participating accreditation bodies have been encountered.

Physical and Mechanical Testing
The final report on jadeite jade proficiency testing programme has been issued. Laboratories identified as outliers have been requested to undertake an investigation and to provide the findings to HKAS.

A proficiency testing programme on the determination of the refractive index of gemstone has been organized and is still underway.

Others
The APLAC APM 017 proficiency testing programme – mass is being organised jointly by HKAS, Hong Kong Association of Certification Laboratories (HKACL), and KAN – the national accreditation body of Indonesia.

APLAC T044 – a proficiency testing programme for textiles is being organised jointly by HKAS and Hong Kong Association of Certification Laboratories (HKACL). Other accreditation bodies have been invited to nominate laboratories for participation.

The final report on APLAC T040 – Coal Proficiency Testing Programme has been issued. All participating laboratories in Hong Kong have obtained satisfactory results.

HKAS has invited accredited laboratories to participate in APLAC T020 and APLAC T021 organised by TAF of Taiwan, China, APLAC T020 involves chemical testing of Portland cement and APLAC T021 involves methanol and sulphur dioxide testing of alcoholic beverage.

Upcoming Training Courses
September 2005
- The Quality Management in the Laboratory Workshop
- The Internal Quality System Audits Workshop
- Preparing for Accreditation in Medical Laboratories
- Medical Laboratory Quality Management Based on ISO 15189
- Internal Auditing of Medical Laboratories to ISO 15189

Interested readers please note that the latest information on training courses is posted on our website at www.itc.gov.hk/hkas.

Change of HKAS Website Address
HKAS has completed its website revamping and the domain name of the homepage has been changed from http://www.info.gov.hk/itc/hkas to http://www.itc.gov.hk/hkas.

If you wish to contribute to the next newsletter or require further information on any of the items in this newsletter, please contact HKAS Executive, 36/F, Immigration Tower, 7 Gloucester Road, Wan Chai, Hong Kong. Tel.: 2829 4840 Fax: 2824 1302 Website address: http://www.itc.gov.hk/hkas E-mail address: hkas@itc.gov.hk