## **CHAPTER 10**

**Government Laboratory** 

Services provided by the Government Laboratory

Audit Commission Hong Kong 30 October 2014 This audit review was carried out under a set of guidelines tabled in the Provisional Legislative Council by the Chairman of the Public Accounts Committee on 11 February 1998. The guidelines were agreed between the Public Accounts Committee and the Director of Audit and accepted by the Government of the Hong Kong Special Administrative Region.

Report No. 63 of the Director of Audit contains 10 Chapters which are available on our website at http://www.aud.gov.hk

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# SERVICES PROVIDED BY THE GOVERNMENT LABORATORY

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# SERVICES PROVIDED BY THE GOVERNMENT LABORATORY

### **Executive Summary**

1. The Government Laboratory (GL) provides a broad range of analytical, advisory and forensic services to enable government bureaux and departments (B/Ds) to meet their responsibilities. In 2014-15, the financial provision of the GL is \$436 million. As at 31 March 2014, the GL had about 460 professional, technical and supporting staff. Headed by the Government Chemist, the GL is organised into three Divisions, namely the Analytical and Advisory Services Division (AASD), the Forensic Science Division (FSD), and the Administration Division. The former two Divisions are further divided into 27 Sections. The AASD performs statutory testing as the referee analyst under a number of ordinances and regulations. It also provides a wide range of chemical testing and advisory services to B/Ds and public institutions. The FSD provides forensic science services to the criminal justice system. The Audit Commission (Audit) has recently conducted a review of the services provided by the GL.

#### **Provision of laboratory services** to user bureaux and departments

2. **Turnaround time of services.** Many requests for laboratory tests need to be performed in a timely manner. The work performance of the GL is published in its Controlling Officer's Report (COR). The GL sets performance targets expressed primarily as a compliance rate, i.e. the percentage of completion of case submissions from its user B/Ds within a specified turnaround time for each type of testing service. Audit found that the practices used for counting the actual turnaround time were not uniformly adopted by individual Sections of the GL and the actual turnaround times of some types of testing had been excluded from the calculation of work performance. Audit also found that the target turnaround times of the sub-categories of services managed by individual Sections of the GL were

well above their actual turnaround times, thus accounting for the high compliance rates achieved. In spite of the high compliance rates of turnaround times, results of Audit's survey of July 2014 on 17 user B/Ds (the Audit Survey) revealed that there were requests from some user B/Ds for expediting the GL's services to better serve their operational needs (paras. 2.4, 2.5, 2.11 to 2.14, 2.19 and 2.20).

3. *Quality assurance.* Audit examination of the GL's internal quality audit reports revealed that the FSD had reported root cause analysis in the summary report of the annual quality audit and submitted to Division Heads for endorsement and necessary actions, while the AASD had not. Audit reviewed the root cause analyses conducted by the FSD and noted that some of these analyses were not thoroughly carried out. Audit analysis of the "non-conformities" and "areas worth improvement" identified by the GL's quality audits revealed some irregularities common among different Sections and some recurring year after year (paras. 2.32 to 2.34 and 2.37).

4. **Coordination with user B/Ds.** To promote effective coordination and facilitate regular consultations, the GL signed a Memorandum of Understanding (MOU) with the Hong Kong Police Force (HKPF) in 2000 and the Customs and Excise Department (C&ED) in 2003. In the Audit Survey, the HKPF and the C&ED considered that the MOU was useful for the GL to understand their needs and there was a need to review the MOU on a regular basis. Of the 15 surveyed B/Ds without such an MOU, four agreed that it would better serve their operational needs if MOUs were signed with the GL. Furthermore, seven of the 17 surveyed B/Ds considered that the GL could provide more types of testing services. Four B/Ds considered that the GL could provide more tests for each type of service (paras. 2.42, 2.45, 2.46 and 2.52).

#### **Outsourcing of laboratory services**

5. *Tender evaluation and contract administration*. Since 2008, the GL has outsourced some of its regular food surveillance testing work to local accredited laboratories. In 2013-14, about 120,000 food tests were outsourced at a total contract sum of \$2.63 million, accounting for some 60% of the AASD's routine food testing work (or 17% of the AASD's testing work). The GL outsourced a total

of 17 food testing contracts in 2013-14. Of the four private laboratories involving outsourcing by the GL, one was awarded 97% of the food testing (in 13 separate contracts). Audit considers that reliance on a dominant contractor for the food testing may pose concentration risks to the GL. Audit also noted that the past performance of laboratories (such as late reporting of test results or warnings issued) had not been taken into account in tender assessment (paras. 3.5, 3.9, 3.10 and 3.15).

6. *Monitoring contractor performance.* To safeguard the quality of outsourcing services, the GL regularly monitors the performance of contractors. During each contract period, the Chemist-in-charge conducted at least one routine on-site inspection. The on-site inspections were normally announced one or two days in advance. There is a need for the GL to consider introducing unannounced inspections to enhance the monitoring of contractor performance. Although the GL formulated in 2011 a comprehensive checklist as a guide for inspections, this checklist was not used by GL staff. Audit considers that using the checklist by different inspection teams would help ensure completeness and consistency (paras. 3.18 to 3.21).

7. Post-implementation review (PIR) of outsourcing. Audit found that the GL's outsourcing had improved the turnaround times tremendously in conducting food tests. The turnaround times in conducting outsourced food tests were much shorter than those for in-house food tests. After six years of implementation since 2008, it is timely for the GL to conduct a PIR on the outsourcing of the laboratory testing so as to take stock of the position and plan the way forward. The Audit Survey also found that some user B/Ds would like to outsource the laboratory services to private laboratories (directly by themselves or by the GL). Additionally, Audit noted that some user B/Ds wanted to have staff seconded from the GL. The Secretary for Food and Health has allocated a recurrent funding of \$12 million a year to the GL for outsourcing its routine food tests to commercial laboratories. Audit however found that of the \$10.33 million expenditure on outsourcing in 2013-14, only \$2.69 million (26%) was spent on contract payments to contractors, while \$7.64 million (74%) was spent on items not directly related to outsourcing (paras. 3.36, 3.37, 3.42 to 3.44).

#### Management of chemicals, samples, exhibits and equipment

8. **Stock management of chemicals.** The GL spends about \$120 million a year on purchasing equipment and chemicals. Audit noted that there were stock discrepancies between stock balance reports and stocktaking records. Audit selected 20 items with discrepancies for the year 2014 and checked whether the discrepancies were properly adjusted. It was found that the stock balances of six items had not been adjusted accordingly. Audit conducted a stocktaking exercise on 28 July 2014 at the GL main store, and found discrepancies in 20% of the items checked. Audit also noted that no expiry dates of chemicals were recorded in the stock system. There was no requirement for the GL's Sections to conduct stocktakes regularly on the stock held and to check the expiry dates of the stock items (paras. 4.2, 4.4 to 4.7, 4.9 and 4.14).

9. *Handling of samples and exhibits.* Many of the samples received by the GL are formal exhibits used for prosecution purposes. The reports are required to be delivered, and the exhibits to be returned, to the user B/Ds. Taking 28 July 2014 as the cut-off date, Audit found that 32% of the cases with reports and/or exhibits had not been collected for over 3 months after the completion date (including 14% over one year). Audit noted that there were no stocktaking requirements stipulated in the quality manuals for samples/exhibits, nor were there any guidelines for handling exhibits remaining uncollected by user B/Ds for a long time. Audit also found cases in which the exhibits were only collected a long time (e.g. over 1 year in 56 cases) after the reports were completed. As such, the GL may need extra storage space/facilities to keep these long-outstanding exhibits (paras. 4.23 to 4.25).

10. Maintenance of equipment. The GL has been using the service of the Electrical and Mechanical Services Trading Fund (EMSTF) to maintain and repair its equipment since the establishment of the EMSTF in 1996. The GL entered into a five-year Service Level Agreement (SLA) with the EMSTF starting from 1 April 2001. Under the current SLA (1 July 2011 to 31 March 2016), the GL would pay the EMSTF a maintenance fee of about \$40.38 million over the period according to the equipment list. The current SLA will expire on 31 March 2016. In April 2014, the GL was exploring the way forward and the strategy for the maintenance of all equipment in use. In this regard, the GL identified some major challenges, including: (a) the warranties of many items of scientific equipment would expire in the next few years; (b) the additions to the equipment list for maintenance services might increase the SLA fee substantially; and (c) for some scientific equipment with advanced technology, the EMSTF might not have the required expertise to provide maintenance services (paras. 4.28, 4.30, 4.32 and 4.35).

#### Way forward

11. Given its limited resources and the wide spectrum of government services that require its support, the GL is facing challenges to continuously improve its efficiency and cost-effectiveness in the provision of laboratory services. The frequent occurrence of emergency incidents (notably food incidents) in recent years has also put pressure on the GL in providing support to various B/Ds in dealing with such incidents. The GL is meanwhile reviewing its way forward to meet the challenges (paras. 5.2 and 5.5).

#### Audit recommendations

12. Audit recommendations are made in the respective sections of this Audit Report. Only the key ones are highlighted in this Executive Summary. Audit has *recommended* that the Government Chemist should:

Provision of laboratory services to user B/Ds

- (a) critically review the GL's compilation of performance information on turnaround times reported in the COR to ensure that it is clearly and fairly presented (para. 2.22(a));
- (b) continue to make efforts to shorten the target turnaround times of laboratory services to help user B/Ds better meet their operational needs (para. 2.22(e));
- (c) take measures to ensure that root cause analyses are thoroughly conducted and the results are documented, so as to identify appropriate corrective actions (para. 2.38(b));
- (d) liaise with user B/Ds for signing an amplified version of MOU with the GL in order to better define and predict the service needs and facilitate effective planning of the use of resources (para. 2.55(c));

**Outsourcing of laboratory services** 

- (e) consider the need to limit the number of outsourcing contracts that each private laboratory may be awarded so as to reduce concentration risks (para. 3.16(a));
- (f) introduce unannounced on-site inspections, and remind the inspecting officers to use the inspection checklist to properly document the results for each inspection (para. 3.22(a) and (b));
- (g) conduct a PIR on the outsourcing of laboratory services, including exploring the feasibility of more outsourcing of laboratory services and staff secondment to user B/Ds, and reviewing the propriety of charging to the outsourcing vote items which are not directly related to outsourcing (para. 3.46(b) and (c));

Management of chemicals, samples, exhibits and equipment

- (h) ensure that the expired stocks are disposed of periodically and the stock lists are updated promptly (para. 4.18(d));
- (i) provide more management information for monitoring long-outstanding cases pending collection by user B/Ds (para. 4.26(b)); and

#### Way forward

(j) take on board the audit observations and recommendations in this Audit Report in taking forward the GL's long-term strategic development plan (para. 5.6).

#### **Response from the Administration**

13. The Government Chemist agrees with the audit recommendations.

#### **PART 1: INTRODUCTION**

1.1 This PART describes the background to the audit and outlines the audit objectives and scope.

#### Background

1.2 The Government Laboratory (GL), with the Food and Health Bureau as its housekeeping Bureau, provides a broad range of analytical, advisory and forensic services to enable government bureaux and departments (B/Ds) to meet their responsibilities for law and order, public health and safety, environmental protection, government revenue, consumers' interests, and implementation of government policies. It also provides similar services to other statutory bodies. Appendix A shows the main services provided by the GL.

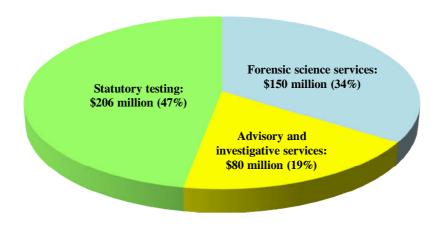
1.3 The GL provides services to B/Ds free of charge. It may also provide scientific services to statutory bodies and the private sector on a full-cost recovery basis, provided that its main functions are not affected.

- 1.4 The GL provides services under the following three categories:
  - (a) *Statutory testing.* The Government Chemist discharges statutory functions as referee analyst under various ordinances and regulations;
  - (b) *Advisory and investigative services.* The GL provides a wide range of chemical testing and advisory services to B/Ds and public institutions; and
  - (c) *Forensic science services.* The GL provides forensic science services to the criminal justice system.

1.5 In 2014-15, the financial provision of the GL is \$436 million. Figure 1 shows the financial provision for each category of services.



# Financial provision for the GL (2014-15)



Source: GL records

#### Mission of the GL

1.6 The GL's mission is to provide our community with quality analytical, forensic and advisory services achieved through advancing measurement science and standards. The GL strives to:

- (a) keep up with the latest development in measurement science and technology;
- (b) be prepared to meet the needs of community;
- (c) strengthen international collaborations; and
- (d) develop metrology in chemistry and biology.

1.7 The GL aims to be a leading laboratory in the region offering significant contributions to the testing community at large. It actively participates in the activities organised by the international and regional metrological organisations and offers necessary support to the local testing and certification sectors.

#### Organisation of the GL

1.8 As at 31 March 2014, the GL had about 460 professional, technical and supporting staff. Headed by the Government Chemist, the GL is organised into three Divisions, namely the Analytical and Advisory Services Division (AASD), the Forensic Science Division (FSD), and the Administration Division. The former two Divisions, each headed by an Assistant Government Chemist, are responsible for providing laboratory testing services. These two Divisions are further divided into four Groups and 27 Sections according to different scientific disciplines (such as biochemical sciences, environmental chemistry, forensic toxicology, etc.). Reporting to a Group Head at the Chief Chemist level, each Section is headed by a Senior Chemist who is supported by several Chemists and Science Laboratory Technologists (SLTs). Appendix B shows an extract of the GL's organisation chart. Appendix C shows the number of staff and the workload of the GL for the past five years.

1.9 The headquarters of the GL is situated in Homantin. It also has six satellite laboratories which are spread out in different locations. Of the 27 Sections of the GL, 18 are located in Homantin headquarters and 9 in the satellite laboratories.

#### AASD

1.10 The AASD performs 11 categories of statutory testing (see Appendix D for details) as the referee analyst under a number of ordinances and regulations, including:

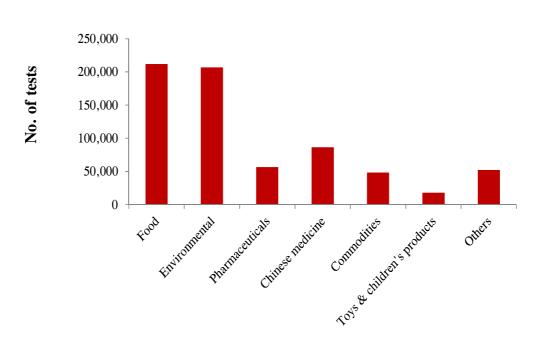
- (a) analysis of food products for regulatory compliance (e.g. under the Public Health and Municipal Services Ordinance Cap. 132);
- (b) examination of western and Chinese medicines for registration and quality control (e.g. under the Pharmacy and Poisons Ordinance Cap. 138);
- (c) testing of dutiable commodities for tariff classification (under the Dutiable Commodities Ordinance Cap.109);

- (d) assessment of toys, children's products and consumer articles for health and safety hazards (e.g. under the Consumer Goods Safety Ordinance – Cap. 456);
- (e) determination of tar and nicotine yields in cigarettes (e.g. under the Smoking (Public Health) Ordinance Cap. 371);
- (f) analysis and authenticity tests on consumer products, in particular those related to valuable goods (e.g. under the Trade Descriptions Ordinance Cap. 362); and
- (g) verification of products and measuring equipment (under the Weights and Measures Ordinance Cap. 68).

1.11 The AASD also provides 10 categories of advisory and investigative testing services (see Appendix D for details) to the Government in the management and monitoring of the environment, and in the enforcement of various pollution control measures. Under this service category, chemical testing of air, water and waste sample for a variety of pollution level indicators constitutes the main activities. Other activities include examination of seepage samples and feed-stocks, and identifying products made from endangered species.

1.12 In 2013, the AASD performed 421,335 statutory tests and 258,973 tests in respect of advisory and investigative services. Figure 2 shows the number of tests completed by the AASD in 2013.





Number of tests completed by the AASD (2013)

Category of testing services

Source: GL records

#### FSD

1.13 The FSD provides 18 categories of forensic science services (see Appendix D for details) to:

(a) law enforcement departments such as the Hong Kong Police Force (HKPF), the Customs and Excise Department (C&ED) and the Immigration Department. The services include examination of crime scenes, biochemical grouping (DNA profiling), trace evidence, accident reconstruction, handwriting examination, and statutory-based analysis of controlled drugs and poisonous substances; and (b) the Department of Health (for the Methadone Maintenance Scheme), the Social Welfare Department, the Correctional Services Department and other organisations requiring urinalysis monitoring service.

1.14 In 2013, the FSD investigated 61,103 cases (including 42,158 urinalysis cases) and attended 474 crime scenes. Figure 3 shows the number of cases (apart from urinalysis cases) investigated by the FSD in 2013.

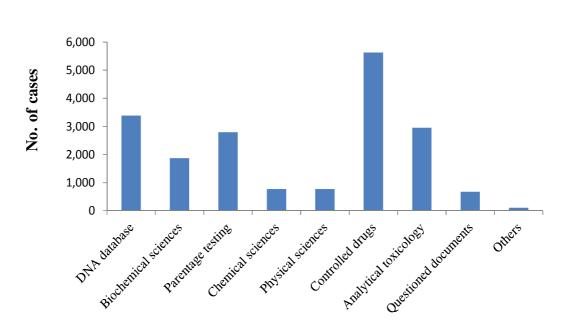


Figure 3

Number of cases investigated by the FSD (2013)

**Category of testing services** 

Source:	GL records
Remarks:	42,158 urinalysis cases are not included.

#### Audit review

1.15 *Audit review of 2002.* In March 2002, the Audit Commission (Audit) completed a review to examine the operations of the GL (the 2002 Audit Review). The review found that there was room for improvement in a number of areas including turnaround time of services, coordination with user B/Ds, and maintenance of equipment. In particular, the review recommended the GL to explore the option of outsourcing its routine analytical testing services to accredited laboratories. The review results were included in Chapter 4 of Director of Audit's Report No. 38 of March 2002.

1.16 Some 12 years have elapsed since the 2002 Audit Review. Audit has recently conducted a review to follow up the implementation of the 2002 Audit Review's recommendations, and examine the measures (including outsourcing of laboratory services) taken by the GL to improve the efficiency and effectiveness of its services to user B/Ds. In conducting this review, Audit conducted a survey (Audit Survey) to gather information from 17 major user B/Ds on the quality of services provided by the GL as well as the related coordination mechanism. The audit review focused on the following areas:

- (a) provision of laboratory services to user B/Ds (PART 2);
- (b) outsourcing of laboratory services (PART 3);
- (c) management of chemicals, samples, exhibits and equipment (PART 4); and
- (d) way forward (PART 5).

Audit has found room for improvement in the above areas, and has made a number of recommendations to address the issues.

#### Acknowledgement

1.17 Audit would like to acknowledge with gratitude the assistance and full cooperation of the staff of the GL and the 17 user B/Ds (see para. 1.16) during the course of the audit review.

#### PART 2: PROVISION OF LABORATORY SERVICES TO USER BUREAUX AND DEPARTMENTS

2.1 This PART examines the GL's provision of services to user B/Ds, focusing on the following areas:

- (a) turnaround time of services (paras. 2.2 to 2.23);
- (b) quality assurance (paras. 2.24 to 2.39);
- (c) coordination with user B/Ds (paras. 2.40 to 2.56); and
- (d) handling emergency incidents (paras. 2.57 to 2.63).

#### **Turnaround time of services**

2.2 The GL is committed to achieving the goal of valid analytical measurements and quality forensic examination service that is impartial and The AASD provides a wide variety of analytical, investigative, and accurate. technical advisory services in the field of applied chemistry and related scientific disciplines to B/Ds, public institutions and official international organisations. The services offered by the AASD are classified under 11 categories of "statutory testing" services and 10 categories of "advisory and investigative services". Additionally, 18 of the 21 categories of services have sub-categories of testing services (see Appendix D for details). The FSD provides a comprehensive range of forensic investigative services to the law enforcement departments in Hong Kong. The services offered by the FSD are classified under 6 categories of services managed by the Criminalistics and Quality Management Group and 12 categories of services managed by the Drugs, Toxicology and Documents Group (see Appendix D for details).

2.3 The GL classifies the user B/Ds' testing requirements as urgent service requests or non-urgent ones. For urgent requests, the tests would be completed within two days to support user B/Ds in response to emergency situations or public health safety concerns (such as food incidents). For example, the AASD handled some 250 urgent cases in 2013.

#### Setting of performance targets

2.4 Many requests for laboratory tests need to be performed in a timely manner. The work performance of the GL is published in its Controlling Officer's Report (COR) and is presented by test category with the volume of testing and the performance target. The COR generally showed a high rate of compliance with its performance targets.

2.5 To measure and manage GL's ability to meet the user B/Ds' demands, the GL sets performance targets expressed primarily as a compliance rate, i.e. the percentage of completion of case submissions from its user B/Ds within a specified turnaround time (Note 1) for each type of testing service.

#### Databases of test sample information

2.6 The GL maintains two web-based application systems for storing the centralised database of test sample information, one for AASD's samples and the other for FSD's samples. Details of test samples received by the AASD are input into the Sample Information Management System (SIMS) while details of those received by the FSD are input into the Extended Sample Information Management System (ESIMS). Both the SIMS and the ESIMS are used by GL staff for making enquiries and tracking of the status of the testing. The design of the systems is to enable the GL staff to make use of the system information to respond to user B/Ds' enquiries of the laboratory testing services.

2.7 The information stored in the databases of both systems includes data such as reference/case number, date of receipt, sample description/category, responsible section, number of tests and the target turnaround time. The centralised database information is eventually copied (downloaded) to the corresponding Sectional databases.

**Note 1:** *Turnaround time is the case-completion time defined as the number of working days between the date of receipt of the exhibits/case at the GL and the date that the exhibits/report are available for return to the user B/D concerned.* 

2.8 The Section users responsible for the input of the individual data would update their own Section's database with data such as the test report/certificate date and the Chemist code. The AASD Section users subsequently transfer (upload) the completed data records back to the SIMS which would be aggregated and summarised in various statistical reports generated for the AASD. The FSD Section users use the Sectional databases to generate the statistical reports.

2.9 Management reports are regularly generated by the systems. Year-end progress review reports are generated for preparing the COR. Quarterly progress reports are generated for reporting to the relevant bureaux. Monthly statistical returns/Section reports, including the returns for the Divisions showing the percentage of samples that achieved the target turnaround time, are generated for internal discussion during the Divisional Management Meetings of the AASD and the FSD.

#### Audit analysis of actual turnaround time

2.10 Audit Review. The 2002 Audit Review (see para. 1.15) noted that for some service performance, the GL could set more challenging targets given the fact that their actual performance had consistently been well above the targets set. In this review, Audit reviewed the 2013 COR compiled by the GL. The COR listed 39 categories of testing, with actual compliance rate well above 90% for substantially all of the categories (see Appendix D). Of the 39 categories of testing disclosed in the COR, 18 have sub-categories. These 18 categories with sub-categories are for "statutory testing" and "advisory and investigative services" (see paras. 1.4 and 2.2). According to the GL, different samples require different analytical procedures, thus different reporting time applies for each sub-category. The quoted number of working days for a specific category in the GL's COR represents an average of reporting time for the different types of samples/test requests within the category, while the target and actual compliance rates, expressed in percentages, represent the total compliance rate of the concerned samples/test requests within a particular category against their sub-categories' respective target turnaround times (not disclosed in the COR). In other words, for the categories with sub-categories, the average reporting time quoted in the COR is for reference only, but not used for measuring the compliance rate.

2.11 According to Financial Services and the Treasury Bureau Circular Memorandum 12/2013, Controlling Officers should make sure that information set out in the CORs is substantiated and accurate, and also satisfy themselves that proper performance records are maintained and, as far as practicable, can be validated. Audit reperformed the calculations of the compliance rate for 2013, but the results did not match or could not be reconciled to the information reported in the GL's COR. As reported in the COR, while targets were met for all categories of laboratory services, the actual compliance rates for 20 of these categories as calculated by Audit were lower than the reported achievements. Audit expressed concerns to the GL that data in the GL systems did not seem to support the information reported in the COR. In response, the GL provided additional information to Audit for reconciling the differences. According to the GL, the difference between audit calculations of the compliance rate and that reported in the COR was very much due to the differing practices of the Sections in counting the number of days taken to provide the services. Audit counted the day of receipt of test sample consistently while some Sections excluded the day. While the difference was not significant for the targets with longer turnaround time, it made a significant difference for those with short turnaround time. According to the GL, the GL comprised many Sections which provided different services to different user B/Ds, there were many differences among them due to historical and operational reasons. Another reason noted by Audit was that some types of testing had been excluded by some Sections of the GL in the calculation of its work performance reported in the COR.

2.12 Key findings arising from the audit analysis of the reconciliation of the differences are summarised in Table 1.

#### Table 1

#### Key audit findings

	Audit findings	Audit comments			
turnarc	practices for counting the actual bund time were not uniformly d by the individual Sections 1).	The practice for counting the actual turnaround time should be formally adopted by the GL and consistently applied to all its Sections.			
types of the ca reporte exclusi of the	• The actual turnaround times of many types of testing had been excluded from the calculation of work performance reported in the COR (Note 2). Such exclusions were made at the discretion of the Sections and not properly documented for management review.				
Source: A	udit analysis of GL records				
Note 1: E	Examples of the different practices include	de:			
(0	(a) some Sections counted the day of receipt of test samples (the first day) as one day, but some did not; and				
(b	the number of working days taken for the testing was approximated by multiplying the number of calendar days by the factor of 5/7, except one Section which deducted the actual holidays in calculating the working days.				
Note 2: T	Note 2: Types of testing excluded from the calculation of turnaround time are:				
(0	(a) some Sections included proficiency tests for calculating the work performance, but some did not;				
(b		some Sections included samples from the Hospital Authority for calculating the work performance, but some did not;			
(0	some Sections excluded cases which required no further action (NFA), but some Sections included them for calculation, taking the day confirming the NFA status as the sample-out day;				

#### Table 1 (Cont'd)

(d)	some newly introduced testing services which were more complicated in nature and longer turnaround times were required;
(e)	some non-routine samples;
(f)	some microbiology samples involving inter-laboratory exercises;
(g)	some mutually-agreed annual targets or pledges, made at regular meetings of the Drug Related Working Group (comprising officers from the GL and the C&ED);
(h)	fire investigation, miscellaneous chemical investigation, and some trace evidence tests;
(i)	complicated cases requiring longer turnaround times;
(j)	ad-hoc research and development work; and
(k)	hair drug tests and drug urinalysis tests conducted under the Healthy School Programme.

2.13 Audit also noted that different Sections in the AASD input into the SIMS different target turnaround times for different sub-categories, which were used by the system to generate the compliance rates. When the testing turnaround time was shorter than that specified for the relevant sub-category, that testing was considered to have met the relevant target turnaround time set in the COR. However, these target turnaround times had not been approved by the Government Chemist. It appeared that these target turnaround times for the sub-categories were input at the discretion of the Sections concerned.

2.14 Audit calculated the average target turnaround times of the sub-categories that made up the categories based on the data captured by the SIMS and found that some of them were actually well above the average turnaround times specified in the COR (see Table 2).

#### Provision of laboratory services to user bureaux and departments

#### Table 2

#### Longer average target turnaround times against those specified in the COR (2009 to 2013)

		Average		categories	get turnard that mad orking da	e up the c	
		turnaround time specified in the COR					
		(Working day)	2009	2010	2011	2012	2013
A. \$	Statutory testing						
1	Other food samples	19	35	38	33	32	33
2	Pharmaceuticals (quality control — Note)	14	46	49	51	47	33
3	Pharmaceuticals (registration)	30	36	36	35	37	40
4	Toys and children's products	15	17	16	17	16	17
<b>B.</b> A	Advisory and investi	gative services					
5	Air pollution samples for litigation purposes	18	35	36	36	37	34
6	Field investigation (air pollution) samples	12	15	15	16	15	15
7	Water quality monitoring samples	20	25	25	25	24	24
8	Environmental waste samples for litigation purposes	12	20	22	24	19	14
9	Miscellaneous — other samples	25	43	54	68	72	60

Source: Audit analysis of GL records

*Note:* For an illustration of the calculation of the average target turnaround time, please see Appendix E. It can be seen that the category "pharmaceuticals (quality control)" comprised 34 sub-categories with target turnaround times ranging from 2 to 180 working days.

2.15 Audit found that the target turnaround times set by the Sections for the sub-categories that were included in a category of services could be substantially different (sometimes longer) than the average shown in the COR. Taking "Pharmaceuticals (quality control)" (i.e. Item 4 at Appendix D) as an example, the average turnaround time specified in the COR was 14 working days. However, if a weighted average had been taken to calculate the target turnaround time of all the tests performed in the 34 sub-categories within the category, the average target turnaround time in 2013 would have been 33, and not 14 working days (see Item 2 in Table 2). Audit selected the category "Pharmaceuticals (quality control)" for case study to illustrate the reconciliation of the differences between Audit's calculations and those of the GL for 2013. Audit found from the case study that:

- (a) not all the test requests had been included for calculating the compliance rate;
- (b) the target turnaround times of the sub-categories were generally much higher than the actual turnaround times; and
- (c) the turnaround time stated as an average in the COR was not the benchmark used to measure the compliance rate of the sub-categories.

Details are given in Case 1 at Appendix F.

2.16 In general, setting longer target turnaround times would make it easier for the GL to meet the target compliance rates set in the COR. Audit considers that the GL needs to take measures to ensure that the target turnaround times for the sub-categories input into the SIMS are subject to regular verification and management review, and that the range of target turnaround times used by the Sections for the sub-categories may be more accurate and descriptive than the average target turnaround times for reporting in the COR.

#### Management information for user B/Ds

2.17 As mentioned in paragraph 2.6, the SIMS and the ESIMS are used by the GL for handling user B/Ds' enquiries on related testing information and status checking of the testing. They had been developed for many years. However, Audit found that:

- (a) the SIMS and the ESIMS were not designed for providing comprehensive information as they could not readily generate information on the actual turnaround time of each test category;
- (b) it took quite a long time to extract accurate information required for audit analysis. Some data needed to be extracted from records of individual Sections (i.e. they were not readily available from the centralised systems); and
- (c) during the process of audit analysis, Audit found some doubtful/illogical cases with the sample-in dates later than the sample-out dates. Upon enquiry, the GL informed Audit in September 2014 that the ESIMS contained some system bugs, and hence it was not used for generating performance reports. However, the doubtful/illogical cases were more likely due to errors in data entry.

For better management control purposes, Audit considers that the SIMS and the ESIMS need to be enhanced in order to provide more readily comprehensive management information for the GL.

#### GL's customer surveys

2.18 The GL seeks annual feedbacks from its user B/Ds through questionnaire surveys. The feedbacks shall be analysed and used to improve the management system testing and calibration activities as well as customer services.

2.19 Audit examination of these customer surveys for the past three years revealed that there were requests for expediting the GL's services from some user B/Ds in order to better serve their operational needs (see Table 3 for details).

#### Table 3

Examples of requests for	expediting the GL's services
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User B/D	Comments on the services provided by the GL	Response by the GL
A	• It expected that Government Chemist's certificate (GCC) could be provided for all cases for examination of drugs within 6 weeks (related to Items 28-35 at Appendix D).	• It would be difficult for the GL to produce the GCCs for all drug cases within 6 weeks irrespective of their case nature and complexity.
	• Some cases had time bar restriction of 6 months and many cases would involve seeking legal advice based on the FSD report which generally required 3 to 4 months to complete (related to Items 35 and 36 at Appendix D).	• The GL understood the specific need in traffic cases. Officers-in-charge of cases were welcome to discuss with relevant Section of the GL on the urgency of any particular case in order that priority and resources could be strategically deployed to meet the challenge.
В	• The GL needed to speed up to provide test results within three weeks or less (related to Item 33 at Appendix D).	• The pledge of urinalysis was 22 working days for 85% of the submitted cases. It needed to be discussed between the management of the two departments if a change in pledge was contemplated.
	• Department B appreciated the arrangement of giving verbal replies over the phone in late cases and wondered if facsimile of the reports could be facilitated.	• It was against the policy of the FSD quality system to fax the reports to user B/Ds.

User B/D	Comments on the services provided by the GL	Response by the GL		
C	• It would be extremely helpful if the total net narcotic content could be stated in each and every chemist's certificate. It was available on most certificates but not all (related to Items 28-30 at Appendix D).	• There were situations where stating such information in the certificate might not be helpful or could even be misleading. The GL would base on their experience and case information in providing total narcotic contents in the GCC. Should the total narcotic content be not given in the GCC, the user B/D concerned was welcome to contact the Chemist to clarify the issue.		

#### Table 3 (Cont'd)

Source: GL records

#### **Results of Audit Survey on turnaround times**

2.20 In the Audit Survey conducted in July 2014 (see para. 1.16), 8 (47%) of the 17 surveyed B/Ds responded that some turnaround time targets were too long for meeting their operational needs. Ten of 17 B/Ds agreed or strongly agreed that it would be beneficial if the GL could consult them more thoroughly on the setting of turnaround time targets. Moreover, 10 B/Ds considered that the testing turnaround time should be shortened in order to improve the GL's services.

2.21 Audit's review in 2002 had already indicated that there was room for the GL to set more challenging turnaround time targets so as to provide better services to its users. Over the years, the GL had made efforts in shortening the turnaround time for some examinations. Nonetheless, Audit considers that there is still scope for improvement in this regard.

#### Audit recommendations

- 2.22 Audit has *recommended* that the Government Chemist should:
  - (a) critically review the GL's compilation of performance information on turnaround times reported in the COR to ensure that it is clearly and fairly presented (e.g. disclosing the range of turnaround times of the sub-categories actually used to measure the compliance rates);
  - (b) establish management controls over the creation of sub-categories and their target turnaround times in the computer systems;
  - (c) fix the system bugs (see para. 2.17(c)) and enhance procedures for validating data input to ensure data accuracy and enable efficient generation of management information;
  - (d) enhance the SIMS and the ESIMS in order to provide more readily comprehensive management information for the GL; and
  - (e) continue with the GL's efforts to shorten the target turnaround times of its services so as to help user B/Ds better meet their operational needs.

#### **Response from the Administration**

2.23 The Government Chemist generally agrees with the audit recommendations. He has said that the GL will:

- (a) review the compilation of performance information;
- (b) enhance the computer and information management systems to facilitate management control and the generation of management information; and
- (c) continue the efforts to improve the target turnaround times of its services and/or the percentages of work meeting these targets.

#### **Quality assurance**

2.24 The GL has adopted the ISO/IEC 17025 (the International Standard – Note 2) quality system and acquired ISO 17025 accreditation under the Hong Kong Laboratory Accreditation Scheme (HOKLAS – Note 3) operated by the Hong Kong Accreditation Service (HKAS).

- 2.25 According to the International Standard:
  - (a) the laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel; and
  - (b) in accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce
- Note 2: This International Standard, jointly published by International Organisation for Standardisation (ISO) and International Electrotechnical Commission (IEC), specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory developed methods. This International Standard is applicable to all organisations performing tests and/or calibrations. It is also applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities.
- **Note 3:** The HOKLAS is an accreditation scheme operated by the Hong Kong Accreditation Service. The scheme is open to voluntary participation from any Hong Kong laboratory, proficiency testing provider, and reference material producer that performs objective testing and calibration, provides proficiency tests, produces reference material falling within the scope of the scheme, and meets the HOKLAS criteria of competence.

necessary changes or improvements. Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

2.26 Under its quality policy, the GL is committed to achieving the goal of valid analytical measurements and quality forensic examination service that is impartial and accurate. The GL shall provide user B/Ds at all times with a service complying with recognised standards of practice. A quality system in line with ISO 17025 has been implemented in the GL to achieve its management objectives.

2.27 The Divisional management system implemented in the AASD and the FSD shall be reviewed separately once a year for its effectiveness in achieving Divisional management objectives and for identifying any need for improvement due to changing external circumstances. This shall be done through the use of the quality policy, quality objectives, audit results, proficiency testing results, client feedback, corrective and preventive action, and management review.

2.28 For the above purpose, Divisional Management Review Meetings chaired by Division Heads shall be convened each year. Notes of meeting shall be prepared and maintained by the Divisional Quality Assurance (QA) Managers. The following shall be specified for any action arising from the meeting:

- (a) the nature and details of the action to be taken;
- (b) the responsible action officer; and
- (c) the scheduled implementation date.

2.29 The Divisional QA Managers are responsible for the follow-up verification of the implementation and effectiveness of the proposed actions. The findings of the follow-up verifications shall be recorded by the Divisional QA Managers and reported to the responsible Division Heads.

2.30 To evaluate the effectiveness of the quality system implemented by the GL in achieving its quality objectives, Audit examined the Management Review Reports of both the AASD and the FSD for the past three years. Audit noted that the established quality systems of the GL were generally operating satisfactorily. However, Audit also noted some areas where improvements could be made. Details are given in paragraphs 2.31 to 2.37.

#### Internal quality audit

2.31 Generally in line with the International Standard, the GL conducts Divisional internal quality audit of the Section's activities annually to verify that its operations comply with the requirements of the Laboratory's quality documents (Note 4), the Security Manual, the Safety Manual, and the accreditation criteria set out in the HOKLAS operated by the HKAS. The Divisional quality audit comprises on-site inspections and reviews of the operation of each Section. The internal quality audit findings are categorised as non-conformities (NCs — Note 5) and areas worth improvement (AWIs — Note 6). A summary report of the annual quality audit will be compiled and submitted by the Divisional QA Managers to Division Heads for endorsement and necessary actions.

2.32 Audit examination of the recent three years' internal quality audit reports of both the AASD and the FSD revealed that quite a number of NCs with the laid-down quality documents as well as AWIs were identified as shown in Table 4.

- **Note 4:** The GL's quality documents include the Laboratory's Quality Assurance Protocol (QAP), Standard Operating Procedures (SOPs) of the AASD and the FSD, Sectional Analytical Methods Manuals, Sectional Work Manuals (SWMs), and Miscellaneous Work Instructions.
- **Note 5:** An NC is a disagreement or an inconsistency with a written clause in the internal quality documents or the HKAS or the HOKLAS related documents by an individual or by the Section.
- **Note 6:** An AWI is an area of concern identified by internal auditors, which may lead to a potential source of NC, or simply suggestions to enhance or further improve on the present quality system. Preventive action may be recommended in the former case.

#### Table 4

	2011 (Note)		2012 (Note)		2013 (Note)		
	AASD	FSD	AASD	FSD	AASD	FSD	
	Number of AWI/NC						
AWI	6	46	22	33	19	26	
NC	0	16	0	30	0	16	
Total	6	62	22	63	19	42	

## Results of internal quality audits (2011 to 2013)

Source: Audit analysis of GL records

#### Root cause analysis

2.33 **Different Divisional practices.** Corrective actions shall be taken to rectify any identified non-conforming work or departures from the documented quality systems. The corrective actions taken shall include the necessary investigations to reveal the root cause of the NC. However, there is no similar root cause analysis requirements in GL's quality manuals in handling identified AWIs. As AWIs are potential sources of NCs, Audit considers it worthwhile for the GL to set down root cause analysis requirements in the GL's quality manuals in handling identified AWIs. In practice, the GL had conducted root cause analysis on both AWIs and NCs identified. However, Audit noted that the FSD had reported such root cause analysis in the summary report of the annual quality audit and submitted to Division Heads for endorsement and necessary actions (see para. 2.31), while the AASD had not.

2.34 *Root cause analysis of some NCs not thoroughly conducted.* As shown in Table 4, the AASD had not identified any NCs in the past three years and it was not its practice to report a root cause analysis on identified AWIs in the summary

*Note:* The internal quality audits of the AASD and the FSD have different audit periods. The former covers the preceding financial year and the latter covers the preceding calendar year.

report for senior management review. Audit's review of the root cause analyses therefore only covered the FSD. Audit noted that some root cause analyses were not thoroughly carried out by the FSD as shown in Table 5.

#### Table 5

#### 2011 2012 2013 AWI NC AWI NC AWI NC Total (No.) (No.) (No.) (No.) (No.) (No.) (No.) 0 10 6 4 2 Root cause not 6 identified (17%)Root cause identified (Note 1): 9 - Overlooking 20 6 12 12 8

28

67

72

167 (100%)

(43%)

(40%)

#### Root cause analysis conducted by the FSD (2011 to 2013)

Source: Audit analysis of GL records

Total

requirements

- Specific causes

(Note 2)

*Note 1: These included cases with genuine root cause.* 

20

46

10

16

Note 2: Examples of specific causes included inconsistent practices in keeping technical records, improper maintenance of quality documents, and improper control of Sectional forms.

14

33

12

30

10

26

6

16

- 2.35 As can be seen from Table 5:
  - in some (17%) cases, root causes were not identified; and (a)

(b) a considerable proportion (40%) of the inadequacies identified in the quality internal audits were due to the overlooking of quality requirements.

2.36 Audit considers that root cause analysis is an important part in the corrective action procedure. Potential causes involve methods and procedures, staff skills and training, consumables, or equipment and its calibration. The GL needs to carry out the root cause analysis thoroughly for future improvement.

### Common types of NCs

- 2.37 Audit analysis also revealed that:
  - (a) some NCs and AWIs occurred in more than one Section. Table 6 shows the details;

#### Table 6

Year	NC/ AWI	Category	Sub-category	Number of Sections involved
2012	AWI	Test and examination methods, and method validation	Format of Analytical Methods Manual	3
2012	NC	Management of test and measuring equipment	Documentation and maintenance of records of training, and authorisation	4
2012	AWI	Quality and technical records	Requirements on preparation of quality and technical records	5

#### NCs and AWIs occurred in more than one Section

Source: Audit analysis of GL records

(b) some common NCs occurred (see Table 7); and

#### Table 7

#### Some common NCs

Type of NC	2011	2012	2013
Inadequate control of external documents	N/A	$\checkmark$	~
Requirements on preparation of quality and technical records not met	~	~	~

Source: Audit analysis of GL records

(c) as NCs and AWIs occurred in a number of Sections and there were some common types of irregularities, Audit considers that the GL needs to implement corrective actions that would prevent the recurrence of these AWIs/NCs.

Upon enquiry, the GL informed Audit in September 2014 that many repeated occurrence of similar NCs and AWIs in the FSD in the period 2011 to 2013 were due to the fact that new quality requirements were introduced as the FSD made its transition to ISO 17025 in 2011. Time was required for GL staff to accustom to the new criteria. In GL's view, the NC and AWI observations were not critical issues and did not invalidate or compromise the quality of the reports or results as already established during the external ISO 17025 quality audits conducted by the HKAS by qualified external technical experts and assessors in the period 2011 to 2013.

# Audit recommendations

#### 2.38 Audit has *recommended* that the Government Chemist should:

(a) consider aligning the Divisional practices in reporting root cause analysis on NCs and AWIs to Division Heads for endorsement and necessary actions;

- (b) take measures to ensure that root cause analyses are thoroughly conducted and the results are documented, so as to identify necessary corrective actions to address the risks relating to the identified NCs and AWIs; and
- (c) step up efforts to implement effective corrective actions to tackle those cases of common types of irregularities of AWIs/NCs.

# **Response from the Administration**

2.39 The Government Chemist agrees with the audit recommendations. He has said that measures were in place to ensure that root cause analyses were conducted so as to identify necessary corrective or preventive actions to address the identified NCs and AWIs.

# **Coordination with user bureaux and departments**

2.40 The GL provides a wide range of laboratory tests on samples from various B/Ds. For the purposes of maintaining the GL's work performance, good communication is required for discussion with user B/Ds on matters such as working relationships, analytical requirements, testing arrangements and procedures, resource constraints, etc.

2.41 The GL holds periodic (annually or quarterly) Senior Management Meetings (SMMs) with major user B/Ds. According to the GL, its staff would sometimes directly discuss with the user B/Ds' senior management for important issues. There would also be frequent liaisons and discussions at Section Head or Chemist level.

## Memorandum of Understanding

2.42 To promote effective coordination and facilitate regular consultations on policy issues and matters of common interests, the GL signed a Memorandum of Understanding (MOU) with the HKPF in 2000. Subsequent to the 2002 Audit Review, another MOU was signed in 2003 with the C&ED to enhance cooperation.

According to the MOU with the C&ED, the GL and the C&ED shall, among others:

- (a) agree on the scope, capacity, and levels of services to enable effective planning of the resources for the provision of services;
- (b) agree on the performance measures and standards to ensure the targets are relevant and the needs of the C&ED are addressed;
- (c) regularly review the scope of services and the associated demand for services to facilitate better planning for use of resources; and
- (d) review the terms of the MOU at a two-year interval.

#### **SMMs**

2.43 Audit noted that the terms of the MOU with the C&ED were comparatively more comprehensive than those of the HKPF. In the 2013 SMM with the C&ED, key service achievements of the 2012 testing were tabulated for review and key service requirements for 2013 to 2015 were projected for mutual agreement. During the SMM, the C&ED enquired about the test services they needed but were not provided by the GL so that it could make a better sample submission plan to the GL as well as the outsourcing arrangements with private laboratories. The C&ED also opined that outsourcing was not the ultimate alternative as test services provided directly by the GL would have the unique advantages of building up information databank and expertise useful for the continuity and improvement measures to support long-term operations.

2.44 For other user B/Ds, the testing targets were mainly based on the pledge in the COR and had been conventionally adopted. According to the GL, the COR targets and the details of testing services including key service requirements would be reviewed and discussed during meetings when necessary. When there was no significant change in the overall testing requirements, the meetings would then focus more on the new service requirements and specific test types/parameters. The user B/Ds may be updated on the progress of service provision if necessary.

## Results of Audit Survey on MOUs with the GL

2.45 In the Audit Survey conducted in July 2014 (see para. 1.16), the C&ED and the HKPF expressed the view that the MOU was useful for the GL to understand their needs regarding the services provided and there was a need to review the MOU on a regular basis. The HKPF also agreed that there was a need to further amplify the MOU.

2.46 Of the 15 surveyed B/Ds that have not signed MOUs with the GL, 4 (27%) B/Ds agreed that it would better serve their operational needs if MOUs were signed with the GL. However, 4 (27%) of the 15 B/Ds considered that there would be difficulties in working out a mutually agreed MOU with the GL.

### Reviewing the service requirements of user B/Ds

2.47 The significant advances in technology in recent years coupled with the introduction of new government policies and regulations involving scientific considerations, the launching of new materials and products in the local market as well as the sophistication of criminal activities have contributed to significant changes in the work patterns of, and methodology employed at the GL. This has led not only to a broader coverage in scope of service provision, a higher degree of specialisation among the professional staff, but also to the installation of a powerful array of modern scientific instruments. Therefore, the GL needs to closely liaise with user B/Ds for planning the service requirements to suit the changing circumstances. In this regard, the Audit Survey showed that some user B/Ds considered that the signing of MOUs with the GL would better serve their operational needs.

2.48 Apart from the signing of MOUs, the GL may also model on the SMM arrangement with the C&ED to hold meetings with the senior management of other user B/Ds. At these meetings, a more comprehensive review of the key service achievements can be conducted to identify difficulties in the existing testing services (e.g. the testing samples, the collection method, testing results, etc.). Such meetings also provide a good opportunity for reviewing effectiveness of the newly introduced services (e.g. hair drug tests).

## Need to review and amplify the MOUs

2.49 Audit noted that, subsequent to the 2002 Audit Review, the GL discussed signing an MOU with a number of user B/Ds in July 2002, October 2002, August 2003 and May 2004 respectively. However, at that time, they did not consider that there was a need to sign such an MOU, but would keep in view the need to do so. For the existing MOUs with the HKPF and C&ED, they had remained unchanged since they were signed in 2000 and 2003 respectively. As far as could be ascertained, there had not been any comprehensive review of the MOU of the HKPF.

2.50 The 2002 Audit Review recommended that the MOU should be amplified in specifying the key service requirements (e.g. objectives, levels and capacity of services required, method of operation, performance measures and standards, etc.). The amplification could refine and predict the user B/Ds' service needs, and enable a more accurate workload forecast. The GL should continue to liaise with the user B/Ds concerned for developing an amplified version of the existing MOU.

#### GL's customer surveys

2.51 Audit examination of the GL's customer surveys for the past three years revealed that there were requests for the GL to provide more training, briefing and sharing sessions on a regular basis from some user B/Ds. Table 8 shows some examples of such requests.

#### Table 8

# Examples of requests from user B/Ds for more training/briefings/sharing sessions by the GL

User B/D	Comments on the training/ briefings/sharing sessions provided/arranged by the GL	Response by the GL
X	• It suggested that the FSD could provide training/briefings to frontline officers with a view to allowing them to have more understanding of the work of the FSD.	• Training could be organised on request, and interested parties might contact the GL for further arrangement.
Y	• It disagreed that the training/ briefings by the FSD of less than 10 hours per year would be sufficient.	• Close liaison would be made with the training unit of the user B/D concerned in arranging more effective custom-made training to their officers.
Z	• Sharing session would be useful for mutual understanding of each department's work and hence hoped that such arrangement would be continued.	• GL supported holding such sharing sessions on an annual basis to strengthen mutual communication.

Source: GL records

## Results of Audit Survey on services/training provided by the GL

2.52 In the Audit Survey conducted in July 2014, 7 (41%) of the 17 surveyed B/Ds would like to see the GL provide more types of testing services. Four (24%) B/Ds considered that the GL could provide additional number of tests for each type of service.

#### **Provision of laboratory services to user bureaux and departments**

2.53 A majority (10 or 59%) of the surveyed B/Ds agreed or strongly agreed that training provided by the GL enabled their staff to understand the laboratory services provided. Nine (53%) B/Ds agreed or strongly agreed that more training provided by the GL could better meet their operational needs.

2.54 In Audit's view, the GL needs to consider expanding the scope of their laboratory services and providing more testing for its user B/Ds. The GL also needs to consider providing more training to user B/Ds.

# Audit recommendations

- 2.55 Audit has *recommended* that the Government Chemist should:
  - (a) strengthen the coordination with the user B/Ds' senior management by conducting in the GL's periodic meetings with them a more comprehensive review of the laboratory services provided, including:
    - (i) providing more information such as key service achievements and the actual turnaround testing times; and
    - (ii) projecting and agreeing on the key service requirements and performance targets;
  - (b) consider amplifying the existing MOUs by including more details such as the scope of services, agreed service levels, performance measurements and monitoring, liaison and coordination, etc.;
  - (c) continue to liaise with user B/Ds for signing an amplified version of MOU with the GL in order to better define and predict the service needs and facilitate effective planning of the use of resources;
  - (d) consider the need to expand the scope of laboratory services and provide more testing for user B/Ds; and
  - (e) consider providing more training to user B/Ds.

# **Response from the Administration**

2.56 The Government Chemist agrees with the audit recommendations.

# Handling emergency incidents

2.57 Emergency incidents refer to those unpredictable events which are caused by unforeseeable factors, resulting in serious damage to or concern of the community. There were quite a number of emergency incidents in recent years, including food incidents such as the radiation contamination of food products imported from Japan following the Fukushima nuclear accident in March 2011, and the plasticiser contamination of a wide variety of Taiwanese food and drinks in June 2011. More recently, in 2014, the gutter oil scandal also posed food safety threat to the general public. The GL was required to render testing and advisory services to support various B/Ds in dealing with these incidents. In general, these emergency incidents arouse great public concerns and time is of the essence in taking effective measures to handle these cases. As the nature of an emergency incident is very often unprecedented, there is no established methodology for providing the laboratory testing services required. Such emergency incidents pose great challenges to the GL in providing the urgent laboratory services necessary to support the handling of the cases.

2.58 The Government Chemist issued a document entitled "Contingency Plan for Major Crises". The scale of crises is classified into three levels, which varies with the importance and scale of the crises. Upon activation of this Plan, the Departmental Emergency Coordinating Centre (DECC) will be set up and activated automatically for coordinating the work in times of crisis. The DECC consists of an Emergency Director, Operation Director, Human Resource Coordinator and Physical Resource Coordinator. The composition of the DECC varies at different levels of crises. Operation procedures are also included in the contingency plan. 2.59 In July 2014, Audit requested the GL to provide for examination the case files containing all relevant documents and correspondence relating to food incidents (e.g. incidents relating to oil fish and radiation contamination of food products). However, no such files were available for audit examination. Upon enquiries, GL staff informed Audit in August 2014 that they did not have a separate file to keep all documents relating to an emergency incident. Audit examined the relevant correspondence files, but could not find any correspondence relating to the emergency incidents.

2.60 Audit noted that the documents relating to an emergency incident were not organised in a separate subject file. In the circumstances, when there are staff changes, it would be difficult for new staff to learn from the past experience. When similar crises occur in the future, the GL's staff might have to work from scratch. The emergency incidents may occur from time to time unpredictably. Prompt actions need to be taken by the GL in order to provide support to various B/Ds to tackle the incidents. Audit considers it important for the GL to learn from the past experiences and the precedent cases. The methodologies in collecting the necessary evidence, methods to obtain the expertise from various fields, difficulties encountered, and the lessons learnt and whether the categorisation and assignment of the three levels of crisis had provided an adequate scaled response to each incident, should be documented properly. This is conducive to the sharing of experience with other staff (especially new staff) and strengthening the GL's capability in handling similar crises in future.

2.61 Upon enquiry, the GL informed Audit in September 2014 that there might not be written communications between users and the GL on food incidents due to the urgent nature of the request (verbal communications are preferred and more direct in many food incidents). All test methods employed by the GL during the incidents were properly validated. These methods together with the validation data and the corresponding test records were documented according to the requirements of the quality system and could be retrieved easily. On the other hand, the full set of "Emergency Case Report" related to emergency services for dealing with incidents involving hazardous chemicals had been maintained since 2001. The reports could be viewed by all professional staff of the AASD. In the yearly Emergency Respond Team Review Exercise, team members were reminded to study the past case reports for reference and selected special cases would be discussed in detail.

# Audit recommendation

2.62 Audit has *recommended* that the Government Chemist should ensure that all relevant documents and correspondence relating to emergency incidents (e.g. food incidents) are properly filed for future reference, so that the experience in tackling such incidents can be shared with all staff concerned in the GL.

# **Response from the Administration**

2.63 The Government Chemist agrees with the audit recommendation. He has said that the "Emergency Case Reports" related to emergency services for dealing with incidents involving hazardous chemicals had been properly maintained. Information about the testing services provided during food incidents, including all testing records and method development and validation data, had also been properly filed.

# PART 3: OUTSOURCING OF LABORATORY SERVICES

3.1 This PART examines issues relating to the GL's outsourcing of laboratory services, focusing on the following areas:

- (a) tender evaluation and contract administration (paras. 3.2 to 3.17);
- (b) monitoring contractor performance (paras. 3.18 to 3.23);
- (c) proficiency testing programmes (paras. 3.24 to 3.32); and
- (d) post-implementation review of outsourcing (paras. 3.33 to 3.47).

## Tender evaluation and contract administration

#### Outsourcing of food testing work

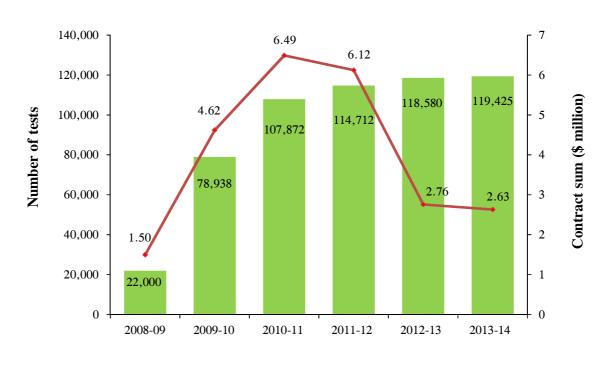
3.2 **2002** Audit Review. In the 2002 Audit Review, Audit noted that the demand for different kinds of analytical and investigative testing services was increasing because of the growing public concern about the environment, food and health. To meet the increasing demand and to further improve the GL performance, Audit had recommended that the GL should explore the option of outsourcing routine analytical testing services to accredited laboratories. The GL welcomed the audit recommendation.

3.3 In 2007, the GL commissioned the Efficiency Unit (EU) to conduct a study to identify outsourcing opportunities for laboratory services of the AASD. The EU study team considered that the outsourcing allowed the AASD of the GL to focus its resources on tackling priorities on policy and complicated testing services, and enabled the private sector to take up those routine services. The study team further proposed the outsourcing and development opportunities for the AASD. The study team recommended that the AASD should outsource those services classified as highly feasible for outsourcing in the first phase (e.g. testing on Chinese medicines and wastewater monitoring) and consider outsourcing other services in the second phase.

3.4 The EU also sought Department of Justice's advice regarding the legal implications/limitations on outsourcing routine testing of the AASD's services. The legal advice was that routine testing not involving law enforcement was not subject to any legislative restrictions.

3.5 Since 2008, the GL has outsourced some of its regular food surveillance testing work (which will not normally result in any legal actions) to local accredited laboratories. The scope covered the testing of food preservatives, heavy metals, additives, pesticide residues, and veterinary drug residues. Since the commencement of outsourcing in 2008 and up to March 2014, the GL had entered into 83 outsourcing contracts with a total contract value of \$24.12 million. The scale of outsourcing activities had increased from 22,000 food tests (involving 2,900 samples) in 2008-09 to around 120,000 food tests (about 13,400 samples) in 2013-14. It accounted for about 60% of the AASD's routine food testing work (or 17% of all the AASD's testing work) in 2013-14. Figure 4 shows the trend of the GL's outsourcing activities. Although the number of tests continued to increase, the total contract sums for outsourcing dropped significantly from \$6.49 million in 2010-11 to \$2.63 million in 2013-14. This is possibly the result of competitive tendering.





GL's outsourcing activities (2008-09 to 2013-14)

#### **Financial year**

Source: Audit analysis of GL records

## GL's Outsourcing Management (OM) Section

3.6 The OM Section (comprising 1 Senior Chemist, 2 Chemists and 4 technical staff), established in 2009-10, is responsible for the planning and management of outsourcing contracts. The Section's annual expenditure was \$4.6 million for 2012-13, \$4.8 million for 2013-14, and estimated to be \$5 million for 2014-15. Its main responsibilities include:

- (a) preparing the tender documents;
- (b) researching the potential service providers;
- (c) assessing the tender;

- (d) preparing check samples;
- (e) conducting on-site inspections; and
- (f) reviewing the test reports of the contract laboratories.

#### Tender evaluation and contract administration

- 3.7 The GL tender procedures for the outsourcing of services are as follows:
  - (a) *Determination of outsourcing contracts.* Each year (normally in November), the Centre for Food Safety of the Food and Environmental Hygiene Department (FEHD) and the GL work out a food surveillance plan and agree on the number of chemical analyses to be conducted for the coming year. According to the test types and timeframe, the GL comes up with an outsourcing plan for the coming year;
  - (b) *Invitation of tenders.* Only laboratories having accreditation from the HKAS are invited for tenders. The OM Section from time to time maintains a list of potential service providers. As at July 2014, the list compiled contained 11 local private laboratories. The Supplies Section of the GL invites the contractors in the list to tender;
  - (c) *Two-envelope approach.* The GL adopts a two-envelope approach to tendering. A tenderer has to submit his technical offer and price offer in separate envelopes;
  - (d) *Tender evaluation.* A tender assessment team is formed to evaluate the tenders received. The team will first conduct a technical assessment and then a price assessment. Tender evaluation is conducted in accordance with a pre-approved standard marking scheme; and
  - (e) *Submission of tender report.* The tender assessment team will submit a tender evaluation report to the Assistant Government Chemist of the AASD and seek approval for awarding the contract to the selected tenderer.

#### Reliance on a dominant contractor

3.8 Since 2008, the GL's outsourcing contracts had been awarded to five private laboratories. Table 9 shows the food tests that had been outsourced to the private laboratories in the past six years.

#### Table 9

Number of tests outsourced by the AASD to the private laboratories	
(2008-09 to 2013-14)	

	Private laboratory					
Period	Α	В	С	D	E	Total
2008-09	18,000 (82%)	_	4,000 (18%)		_	22,000 (100%)
2009-10	62,588 (80%)		11,350 (14%)		5,000 (6%)	78,938 (100%)
2010-11	92,702 (86%)		13,630 (12%)	1,190 (1%)	350 (1%)	107,872 (100%)
2011-12	84,260 (73%)	22,202 (19%)	6,300 (6%)	1,950 (2%)	_	114,712 (100%)
2012-13	30,250 (26%)	62,730 (53%)	_	1,100 (1%)	24,500 (20%)	118,580 (100%)
2013-14	1,040 (1%)	117,020 (97%)	415 (1%)	950 (1%)	_	119,425 (100%)

Source: Audit analysis of GL records

3.9 In 2013-14, of the four private laboratories involving outsourcing, one laboratory was awarded 97% of food testing (in 13 separate contracts). Audit considers that reliance on a dominant contractor for the food testing may pose concentration risks to the GL. If the dominant contractor fails to operate effectively, the food testing work would be severely affected. In order to reduce

such risks, Audit considers that the GL needs to consider limiting the number of contracts awarded to each laboratory for the provision of testing. In response, the GL advised that it would need to seek advice from the Government Logistics Department or other relevant authority on restricting the maximum number of contracts to be undertaken by one contractor. Meanwhile, Audit considers that the GL needs to devise a contingency plan to deal with the situation in case the dominant contractor fails to operate effectively.

#### Short duration of outsourcing contracts

3.10 The GL awarded 17 separate food testing contracts each year during the period 2011-12 to 2013-14. Audit noted that the duration of all the GL outsourcing contracts was no more than one year (see Table 10).

#### Table 10

Duration (Month)	Number of contracts	Percentage
3	2	12%
4 to 6	5	29%
7 to 12	10	59%
Total	17	100%

#### Duration of outsourcing contracts (2011-2012 to 2013-14)

Source: Audit analysis of GL records

3.11 Audit examined the tender exercises of these 17 contracts in 2013-14. Though 12 accredited laboratories were invited to submit their tenders, the average number of tenders received was only about 5 in each tender exercise, i.e. less than half of those invited. Market interest in tendering for these testing services appeared to be on the low side. 3.12 Preparation for tender submission is often time-consuming and costly. This might be a reason for the general lack of market interest in tendering for the GL's outsourcing contracts, especially those which were of small contract sums and short contract duration. The short-term contract arrangement also increased GL's administrative costs arising from frequent contract renewals.

3.13 According to the EU report "A General Guide to Outsourcing" in 2008, "Departments should determine the optimum scope of outsourcing from the point of view of both the department and the potential service providers. Surveys of departments and service providers have identified the loss of economy, efficiency and effectiveness in letting contracts that are too small and have short contract duration." Audit considers that the GL should assess the benefits of bundling services and strike a balance between the benefits and risks involved in engaging contractors. The arrangement of longer-term contracts may provide better incentive for potential service providers to bid the GL's outsourcing contracts. This will also encourage the service providers to invest more in equipment, technology and people, as overhead costs and return on investment can be spread over a longer time period.

## Tender evaluation

3.14 In assessing the tenders, the GL adopts the two-envelope approach — technical assessment (accounting for 40% of the combined score) and price assessment (accounting for 60% of the combined score). For the technical assessment, the experience, number of customer complaints received, competence, personnel, and analytical techniques and facilities of the potential laboratories are taken into consideration.

3.15 Audit analysis of the turnaround time of testing services provided by the outsourced contractors indicated that 6% of the test samples results for the years 2012-13 (762 of 12,848 samples) and 2013-14 (748 of 13,365 samples) were not reported by the contractors to the GL in a timely manner. Warnings of unsatisfactory performance were issued to two contractors in the past two years. However, Audit noted that the past performance of laboratories (such as late reporting of test results or warnings issued) had not been taken into account in tender assessment. As the food testing results have public health implications, timely reporting and quality of the test results are crucial contractual requirements.

Audit considers that the GL should take due account of the past performance of contractors when evaluating future tenders.

# Audit recommendations

- 3.16 Audit has *recommended* that the Government Chemist should:
  - (a) consider the need to limit the number of contracts that each private laboratory may be awarded for the provision of testing services so as to reduce concentration risks;
  - (b) prepare a contingency plan to deal with the situation in case the dominant contractor fails to operate effectively;
  - (c) take measures to increase market interest in the outsourcing contracts (e.g. arranging longer-term contracts); and
  - (d) take due account of the contractors' past performance when evaluating future tenders.

# **Response from the Administration**

3.17 The Government Chemist agrees with the audit recommendations.

## Monitoring contractor performance

3.18 To safeguard the quality of outsourcing services, the OM Section regularly reviews and monitors the performance of contractors on individual contracts. Performance monitoring measures include:

- (a) conducting on-site inspections of the contract laboratory;
- (b) issuing quality check (QC) samples;
- (c) reviewing the contractor's test and quality records; and

(d) checking other matters that affect the delivery of testing services.

#### **On-site** inspections

3.19 During each contract period, the Chemist-in-charge will conduct at least one routine on-site inspection for auditing the relevant test and quality records, as well as inspecting the operation of the contractor for assessing the contractor's technical competence and compliance with contract requirements. Follow-up inspections (if required) will be conducted in cases where irregularities had been found. After the inspection, the inspecting Chemist needs to prepare a report listing significant observations of the inspection and submits it to the Senior Chemist for information.

#### Arrangement of QC samples

3.20 For each contract period, the Chemist-in-charge arranges QC samples (at least two QC samples for each contract) to the contractor for evaluating its performance. According to the contract monitoring schedule of OM Section, relevant controlled samples are planted in a batch of food samples which will be collected by the private laboratories concerned for testing. The Chemist-in-charge assesses the results submitted by the contractor, prepares a summary report and submits it to the Senior Chemist for review.

3.21 Audit found that there was room for improvement in the GL's monitoring measures, as follows:

(a) Announced inspection conducted. In response to enquiries, GL staff informed Audit in July 2014 that the on-site inspections were normally announced one or two days in advance. However, carrying out unannounced inspections might be needed if there is reason to doubt the quality of the contractor's laboratory services. For example, when a laboratory has received a complaint about its testing activities which cast doubt on the laboratory's standards. Audit considers that the GL needs to consider introducing unannounced on-site inspections to see if there is room for improvement in sample storage conditions, handling of tests and calibration items, equipment location and utilisation, etc.;

- Inspection checklist not used. The GL formulated in 2011 a (b) comprehensive checklist as a guide for their inspections. The checklist the management requirements (including organisation, covers management system, document control, etc.), technical requirements (personnel, accommodation and environmental conditions, test and calibration methods, equipment, etc.), and contract requirements (services specifications). The use of the checklist by different inspection teams would help ensure completeness and consistency. However, Audit noted that this checklist was not used by GL staff for facilitating the conduct of inspections and documenting the inspection results; and
- Issuing of QC samples. Audit analysis indicated that for 2013-14, the (c) number of QC samples sent to contractor laboratories did not seem to be correlated with the quantum of the food samples outsourced. For example, in 2013-14, two QC samples each were included among the 1,350 food samples outsourced to one contractor laboratory, and among the 260 food samples outsourced to another contractor laboratory. The QC sample may be an inter-laboratory comparison test sample (such as Food Analysis Performance Assessment Scheme (FAPAS) QC sample -Note 7), spiked sample (Note 8), split sample (Note 9), etc. Audit analysed the 77 QC sample reports of 2013-14, but found that the GL used FAPAS in 69 (90%) QC samples. Audit noted that the FAPAS QC sample is a blend test material which can easily be identified by the contractors. Audit considers that the GL should use more varieties in its QC samples to evaluate the contractors' performance.

- **Note 7:** *FAPAS QC test materials are real food matrices with one or more properties that have been established from the results of laboratories participating in a proficiency test and are used by laboratories as quality control materials.*
- **Note 8:** A spiked sample is a sample that has been added a known amount of analyte (a spike) by the GL. The spiked sample is analysed by a private laboratory. A comparison is made between the laboratory's and GL's known results.
- **Note 9:** A split sample is a sample that is divided into two subsamples. Both subsamples are analysed by a private laboratory. The results are compared.

# Audit recommendations

- 3.22 Audit has *recommended* that the Government Chemist should:
  - (a) enhance the monitoring of contractor performance, for example by conducting unannounced inspections to ensure that the contractors comply with the terms of the contracts;
  - (b) remind the inspecting officers to use the comprehensive inspection checklist to properly document the results for each inspection; and
  - (c) make better use of QC samples for evaluating contractor performance (e.g. issuing QC samples to contractors with reference to the quantum of the food samples outsourced, and making more use of other types of QC samples such as spiked samples and split samples).

# **Response from the Administration**

3.23 The Government Chemist agrees with the audit recommendations.

# **Proficiency testing programmes**

3.24 In order to undertake the GL's outsourcing contracts, private laboratories must get the HKAS's accreditation in the test parameters concerned, and maintain the accreditation status throughout the contract period.

3.25 Accreditation is granted by the HKAS on a test-by-test basis. It will only be granted to a laboratory in respect of a specific test after an expert team has confirmed the laboratory's competence in performing the test through an on-site assessment. After accreditation is granted, the HKAS will continue to monitor the performance of the laboratory through periodic on-site re-assessments, on-site surveillance visits and proficiency testing (PT) programmes. 3.26 A PT programme is an important tool used by laboratory accreditation bodies to assess the competency of field laboratories. The GL, as an accredited PT provider in Hong Kong, has organised PT programmes to provide opportunities for participating laboratories to benchmark and improve their performance in specific testing disciplines. Participation in PT programmes is one of the mandatory requirements for laboratory accreditation. In each PT programme, the GL evaluates the performance of the participating laboratories and issues performance reports to them. Accreditation would be granted upon the satisfactory results of relevant PT programme.

## Need for diversification of the PT programmes

3.27 The GL has provided PT programmes to support the development of the local testing industry. For the past five years (up to June 2014), the GL had organised a total of 18 PT programmes, comprising 15 (83%) programmes on food safety testing, 2 (11%) on environmental testing, and 1 (6%) on forensic science testing. It can be seen that the scope of PT programmes mainly covered the food safety testing category.

3.28 The GL has conducted annual surveys on the needs of the local testing community. Audit examined the survey results for the period 2011 to 2013. Audit found that other than the topic on food testing, the industry welcomed more PT programmes for tests relating to phthalates in plastics, and analysis for air and permanent gases. In order to assist the testing industry in building up the capability and capacity to take up government's outsourcing of laboratory testing of different disciplines, the GL should consider organising more types of PT programmes in the longer term.

## Need to assess the effectiveness of the PT programmes

3.29 Though the GL organised PT programmes periodically, it did not conduct customer surveys for all the programmes. For the past five years (up to June 2014), of the 18 PT programmes organised, the GL conducted customer surveys for only 9 (50%) programmes. In order to measure the achievement of the PT programmes towards their planned objectives, and assess the overall effectiveness of the PT programmes to facilitate future planning, the GL needs to conduct formal evaluation for all the PT programmes conducted so as to identify areas for improvement.

#### Need to promote the PT programmes

3.30 When the GL launches a PT programme, invitations to join the programme are made to local laboratories through the HKAS. Audit noted that there were not many (ranging from 1 to 10) local laboratories participating in each programme. To help enhance the capability of local laboratories, Audit considers that the GL needs to step up efforts to promote the PT programmes (e.g. making all PT programme information accessible to all interested laboratories).

## Audit recommendations

- 3.31 Audit has *recommended* that the Government Chemist should:
  - (a) consider organising more types of PT programmes for different testing disciplines in the longer term;
  - (b) conduct formal evaluation for all the PT programmes organised by the GL so as to identify areas for improvement; and
  - (c) step up efforts to promote the PT programmes organised by the GL.

## **Response from the Administration**

3.32 The Government Chemist agrees with the audit recommendations.

## Post-implementation review of outsourcing

3.33 The introduction of outsourcing is to facilitate the GL to release its resources to focus on new test method development, to cope with new testing work arising from amendments of food legislation and perform other duties including analytical tests for urgent food incidents.

3.34 In 2013-14, the GL's outsourcing increased to about 120,000 tests involving 13,400 samples, accounting for about 60% of its actual routine food testing work and about 17% of all the AASD's testing work.

3.35 Audit notes that the demand for different kinds of analytical and investigative testing services has been increasing with growing public concerns about the environment, and food and health. Audit summarised in Table 11 some of the regular testing work for routine monitoring and analytical investigations conducted by the GL.

#### Table 11

	Category		Number of tests			
			2012	2013		
1	Other food samples (Note)	184,950	185,557	193,840		
2	Water quality monitoring samples	125,592	123,168	121,775		
3	Chinese medicines	80,579	77,784	86,479		
4	Seepage and swimming pool water samples	28,832	38,771	40,068		
5	Pharmaceuticals (quality control)	36,758	35,244	31,657		
6	Cigarette samples	12,504	13,536	13,680		
	Total	469,215	474,060	487,499		

# Examples of regular testing work (2011 to 2013)

Source: GL records

*Note: About* 60% *of the tests had been outsourced.* 

3.36 Audit found that the GL's outsourcing had improved the turnaround times tremendously in conducting food tests (see Table 12). It can be seen that the turnaround times in conducting outsourced food tests were much shorter than those for in-house food tests. Upon enquiry, the GL informed Audit in September 2014 that in general the more routine and less complex food tests were outsourced, and

this might be the reason for the shorter turnaround times for the outsourced food tests. Moreover, the target turnaround times of local laboratories were the required turnaround times stated in the contracts. These turnaround time requirements by design must be shorter than the GL's own target turnaround time, in order to allow for sample pick-up, data review, and all other follow-up work by the GL, before the test results could be released to the user B/Ds concerned.

#### Table 12

	Target turnaround time in conducting food tests			
Food testing	GL (Note)	Local laboratory		
	(Day)	(Day)		
Preservatives	32	10-15		
Heavy metals	35	10		
Pesticides	40	14		
Colouring matter	40	12		
Veterinary drug residues	40	10		
Contaminant — melamine	40	3		

# Target turnaround times in conducting food tests (2013-14)

Source: GL records

3.37 Audit considers that, after six years of implementation since 2008, it is now an opportune time for the GL to conduct a post-implementation review (PIR) on the outsourcing of the laboratory testing so as to take stock of the position and plan the way forward. In this connection, the GL also needs to review whether there is scope for outsourcing more of its laboratory services.

*Note:* The target set by the AASD was that 95% of the cases should be completed within the target turnaround times for different types of services. For urgent samples relating to food incidents, the GL set the target turnaround time at 2 days.

## Results of Audit Survey on outsourcing and staff secondment

3.38 *Opinion on outsourcing by the GL*. In the Audit Survey conducted in July 2014 (see para. 1.16), the FEHD, as the only department that had services outsourced by the GL, strongly agreed that the outsourcing of food testing had not compromised the quality of testing services and had improved the turnaround time of testing services.

3.39 For the other 16 B/Ds with services performed by the GL, 6 (38%) considered that it could better meet their service needs if they could outsource the laboratory testing directly to accredited private laboratories instead of having to go through the GL. Five (31%) B/Ds considered that outsourcing of testing services by the GL would not affect the quality of testing services. Seven (44%) B/Ds considered that outsourcing could improve the turnaround time of testing services. One user B/D indicated that it had enlisted private accredited laboratories and outsourced some testing directly to accredited laboratories as the GL could not fully satisfy its testing needs.

3.40 **Opinion on staff secondment from the GL.** A total of 48 professional or technical staff are currently seconded by the GL to departments. Most of them (38 or 79%) are seconded to the FEHD. In the Audit Survey, two user B/Ds (including the FEHD) strongly agreed that the staff secondment helped them achieve their service objectives. The FEHD further considered that more secondment from the GL could better meet its operational needs.

3.41 For the other 15 B/Ds surveyed that did not have staff secondment from the GL, 6 (40%) considered that it would be helpful if the GL seconded staff to them. However, 6 (40%) B/Ds agreed that there would be difficulties in arranging staff secondment from the GL.

3.42 Audit noted that a number of user B/Ds of the GL would like to outsource the laboratory services to private laboratories (directly by themselves or by the GL). Audit considers that the GL needed to communicate more with these departments to ascertain the feasibility for outsourcing of their laboratory services. Audit also noted that some departments wanted to have staff seconded from the GL. Audit considers that the GL should ascertain the needs of these departments regarding staff secondment.

#### Utilisation of the outsourcing budget

3.43 In November 2008, the Secretary for Food and Health allocated a recurrent funding of \$9 million from his operating expenditure envelope to the GL to fund the outsourcing of testing work for samples of routine food surveillance to commercial laboratories. The OM Section was then established in 2009-10. In November 2009, the Secretary for Food and Health allocated an additional recurrent funding of \$3 million making a total of \$12 million a year to the GL for outsourcing not less than 70% of the routine food tests to the commercial laboratories. In doing so, the Secretary for Food and Health hoped that the GL would provide more assistance and support to the commercial laboratories in upgrading their capabilities and in obtaining accreditation. The budget and expenditure relating to outsourcing from 2009-10 to 2013-14 are shown in Table 13.

#### Table 13

Particulars	2009-10	2010-11	2011-12	2012-13	2013-14
	(\$ million)				
(a) Budget	9.00	12.00	12.00	12.00	12.00
Expenditure					
Contract sum	4.72	6.35	5.95	2.81	2.69
Chemicals	0.92	0.03	1.39	1.93	2.24
Equipment	0.39	0.12	0.22	0.05	1.61
Miscellaneous	1.10	0.43	2.42	0.91	3.79
(b) Total expenditure	7.13	6.93	9.98	5.70	10.33
(c) = (a) - (b) Underspending	1.87 (21%)	5.07 (42%)	2.02 (17%)	6.30 (53%)	1.67 (14%)

# Budget and expenditure relating to outsourcing (2009-10 to 2013-14)

Source: Audit analysis of GL records

3.44 As can be seen from Table 13, the outsourcing budgets had all along been underspent, ranging from \$1.67 million (14%) to \$6.30 million (53%). Audit also noted that the total contract sums for outsourcing dropped significantly from a high of \$6.35 million in 2010-11 to \$2.69 million in 2013-14. In the same period, however, the related expenditure on chemicals, equipment and particularly miscellaneous items had increased significantly. In 2013-14, of the \$10.33 million expenditure on outsourcing, \$2.69 million (26%) was spent on the contract payments to contractors, while \$7.64 million (i.e. \$2.24 million + \$1.61 million + \$3.79 million) or 74% was spent on chemicals, equipment and miscellaneous items.

3.45 Upon enquiry, the GL informed Audit that while the chemicals, equipment and miscellaneous items were not used by contractors under the outsourcing contracts, many of these items were used in support of the local testing industry through conducting in-house method development work and the subsequent technological transfer, as well as providing PT programmes to local testing laboratories. Audit considers it questionable whether such a significant proportion of the budget allocated for outsourcing should be spent on items which were not directly related to outsourcing. The GL needs to critically review the proper use of its outsourcing budget in future.

## Audit recommendations

3.46 Audit has *recommended* that the Government Chemist should conduct a PIR on the outsourcing of the laboratory services to take stock of the position and plan the way forward. In conducting the PIR, the GL should among other things:

- (a) review whether the objective of releasing its resources to focus on new test method development and to cope with new testing work arising from amendments of food legislation as well as urgent food incidents (see para. 3.33) has been achieved;
- (b) in consultation with the user B/Ds, explore the feasibility and desirability of the following options:

- (i) outsourcing more of the laboratory services currently provided by the GL for user B/Ds;
- (ii) assisting user B/Ds to outsource laboratory services themselves; and
- (iii) arranging staff secondment to user B/Ds to meet their laboratory service needs; and
- (c) critically review the propriety of charging to the outsourcing vote items which are not directly related to outsourcing.

# **Response from the Administration**

3.47 The Government Chemist agrees with the audit recommendations.

# PART 4: MANAGEMENT OF CHEMICALS, SAMPLES, EXHIBITS AND EQUIPMENT

4.1 This PART examines the GL's management of chemicals, samples, exhibits and equipment, focusing on the following areas:

- (a) stock management of chemicals (paras. 4.2 to 4.19);
- (b) handling of samples and exhibits (paras. 4.20 to 4.27); and
- (c) maintenance of equipment (paras. 4.28 to 4.39).

## Stock management of chemicals

4.2 The GL spends about \$120 million a year on purchasing equipment and chemicals, and uses an extensive range of scientific equipment in delivering its services. When procuring the equipment and chemicals, the GL follows the requirements of the Government's Stores and Procurement Regulations (SPRs). It also has to adhere to the procedural requirements laid down in the GL's QAP and the SOPs. The QAP is the highest level quality document which outlines the GL's policy on the quality system, whereas the SOPs set out the procedures to be followed when implementing particular aspects of the quality system in individual Divisions. The Supplies Section under the Administration Division is responsible for the coordination of procurement in the GL.

4.3 The Supplies Section is tasked to control the stock of commonly used chemical items using a computer requisition system known as Internal Ordering, Inventory Keeping, External Purchases and Budgetary Control System (IIEB) which has been put in place since 1999. The inventory system basically maintains the list of stock items, keeps track of purchase orders, captures deliveries, facilitates reorder notification, and tracks slow-moving items. Reports are provided for stock management (e.g. stock movement transaction report, stock balance report, slow-moving items and excessive stock report). There are four supplies storerooms for keeping common inventories and consumables used by the GL.

## Review of stock records of the GL main store

4.4 *Stock discrepancies.* Audit examined the stock balance reports generated from the IIEB and the stocktaking records by the Supplies Section of 2013 and 2014. Audit noted that there were stock discrepancies between stock balance reports and stocktaking records as shown in Table 14.

#### Table 14

Year	2013	2014
Number of stock items with discrepancies	206	143
Total number of stock items	488	488
Percentage of stock items with discrepancies	42%	29%

#### Stock discrepancies between stock balance reports and stocktaking records

Source: Audit analysis of GL records

4.5 According to the GL, before the annual stock take, the Supplies Section would print a Stock Balance Reports for checking first. They would mark all the discrepancies found on the report and check against the in and out records in the system and the physical documents to try to reconcile the discrepancies. Audit selected 20 items with discrepancies for the year 2014 and checked whether the discrepancies were properly adjusted. It was found that the stock balances of six items had not been adjusted accordingly (up to September 2014). Audit considers that the procedures under SPRs should be followed in dealing with the stock discrepancies, and a final stock balance report should be printed out and signed by the supervisory staff to ensure that all the discrepancies are rectified and stock records are adjusted.

4.6 *Stock disposal.* Upon examination of the 2013 stocktaking report, Audit found that there were four items marked "item not found" by the staff of Supplies Section. Upon Audit's enquiry, the Supplies Section confirmed that most of the unfound items (mainly chemical items which already expired) were passed to the Safety Officer for disposal. Audit noted that the stock records were not timely updated after the disposal of stock.

4.7 *Audit stocktaking exercise.* Audit conducted a stocktaking exercise on 28 July 2014 at the GL main store. There were 437 stock items listed in the Stock Balance Report as at 28 July 2014. Audit selected 20 (about 5%) of the stock items for checking. Audit found that there were discrepancies for four (20%) of the 20 items.

4.8 According to SPRs 610 and 620(c), departments should keep complete records of the receipt and issue of all stores held in a departmental store unit and post all ledgers promptly, and support each entry of the ledgers by a voucher, the nature and number of which should be recorded against the entry. Audit considers that the GL needs to remind all officers to record and update the store records promptly to avoid any discrepancies. If there are any discrepancies found, prompt action needs to be taken to investigate into the reasons and rectify the records accordingly.

4.9 *Expiry dates of chemicals.* Audit noted that no expiry dates of chemicals were recorded in the IIEB. In the circumstances, it would be difficult for the Supplies Section to monitor the usage of such chemicals stock. Moreover, using expired products may undermine the accuracy of laboratory testing. While the Supplies Officer informed Audit that they regularly checked whether the chemicals had expired, there was no documentation of such checking. Audit considers that the expiry dates of the chemicals should be included in the IIEB for better stock management in order to prevent the use of expired chemicals.

## Stock kept at the user Sections

4.10 According to the SOPs of the AASD and the FSD, Section Head shall conduct regular supervisory checks on items kept in stock under the Section, especially those of high-value items like certified reference materials. The Section Head may also assign officers who are not involved in day-to-day stock keeping to conduct the checks and to investigate any discrepancies found.

#### Management of chemicals, samples, exhibits and equipment

4.11 The user Sections obtain the chemicals/reagents from the Supplies Section. According to the SWMs of the Sections in the FSD, the Section staff (usually an SLT) is responsible for ensuring that chemicals/reagents are not used beyond the expiry date. The SLT also monitors the stock balance to initiate stock replenishment and proposes disposal of expired items for approval by the Senior Chemist concerned. However, no such detailed requirements were found in the SWMs (Note 10) of the Sections in the AASD.

4.12 Audit found in a stocktake of one Section in the FSD that there were 174 solid chemical items and 38 solvent items which had been in the stock list of the Section for over 10 years (some of them even over 20 years). Although no expiry date was marked on the stock list, it is not sure whether the solvents could still be used. They might have already expired but not yet been disposed of. It was also found that 11 solid chemical items and 11 solvent items had already expired but not yet been disposed of. There were four solvent items which were only disposed of over 5 years after their expiry. Upon enquiry, the GL informed Audit in September 2014 that some solvents were very stable in nature and could be used without any problem.

4.13 According to the SOPs of both Divisions, minimum stock levels based on the advice of the user Sections are set for each stock item and are reviewed at a regular interval by the Supplies Section to ensure that an optimum stock is maintained at all times to support the laboratory activities. However, there was no evidence to show that the Supplies Section regularly checked the stock kept by the user Sections or asked the user Sections to file a return on the stock kept. The Supplies Section mainly checked the stock at the GL main store, while the user Sections managed their own stock.

4.14 *Lack of regular stocktakes.* After reviewing the QAP, SOPs and SWMs, Audit found that there were no guidelines on the requirement for the user Sections to conduct stocktakes regularly on the stock held on hand and to check the expiry dates of the stock items.

**Note 10:** The SWMs stipulate the quality control plans for the tests conducted, the sample handling procedures adopted by the Sections and the training modules arranged in the Sections.

4.15 Audit considers it a good practice for the user Sections to conduct regular stocktakes on the chemicals/solvents on hand and dispose of the expired chemicals within a reasonable period of time. Furthermore, as some chemicals are dangerous, special care is needed to handle the disposal of the chemical waste. Audit considers that good stock management can save storage space, prevent the use of expired chemicals and the accumulation of useless but dangerous chemicals. When the stock is disposed of, the stock record should be updated accordingly.

4.16 Audit noted that the last exercise for the disposal of the expired chemicals of the main store and the user Sections was conducted in 2009. No other disposal exercise had thereafter been conducted. Upon enquiry, the GL informed Audit in October 2014 that general chemicals like solvents could be disposed of as chemical wastes to be collected by the authorised contractor every week. However, for the disposal of other specialty chemicals, special arrangements have to be made with the authorised contractor. Up to August 2014, the Safety Officer had received requests from a few user Sections to dispose of 335 chemical/solvent/reagent items under special arrangement. However, the Sections were not required to file any returns regularly on the items to be disposed of under special arrangements to the Supplies Section or the Safety Officer. Audit considers that regular filing of items to be disposed of under special arrangements can help the Safety Officer plan the disposal exercise more effectively and also the Supplies Section to monitor the stock level.

4.17 Audit considers that the GL needs to improve its stock management by conducting regular stocktakes in both the main store and user Sections, disposing of the expired stock items periodically, and updating the stock list promptly.

# Audit recommendations

- 4.18 Audit has *recommended* that the Government Chemist should:
  - (a) ensure that proper stock records are kept in accordance with the SPRs;
  - (b) establish departmental stocktaking guidelines (e.g. procedures before and after the stocktake, and review of stocktake results by supervisory officers), and ensure regular stocktakes are conducted for all stocks;

- (c) include the expiry dates of the items in the stock list of the main store to facilitate better stock management; and
- (d) ensure that the expired stocks are disposed of periodically and the stock lists are updated promptly.

# **Response from the Administration**

4.19 The Government Chemist agrees with the audit recommendations. He has said that for general chemicals and reagents, there might not be a need to keep track of their expiry dates as they were normally chemically stable under storage conditions and their turnover was high. For those reference materials, expiry dates and detailed stock list were kept and regularly reviewed by Sections.

# Handling of samples and exhibits

4.20 According to the QAP and SOPs, all samples and exhibits submitted by user B/Ds should be handled with care. All samples and exhibits are logged in the individual Division's computerised central sample register using unique laboratory numbers for identification (with the AASD using the SIMS and the FSD using the ESIMS). Records of chain-of-custody for regulatory samples/exhibits are maintained. The sample registration officer is required to ensure that all samples submitted are properly sealed to prevent loss or contamination. Proper security can be achieved by storing the samples in locked cabinets or rooms. For items which require registration, plastic bins fitted with locks are used. The names of officers with access to the exhibits must be properly recorded.

4.21 According to the SOPs, the custody of the exhibits during the course of examination lies with the examiner in possession of the samples/exhibits (i.e. either the reporting officer or his/her subordinates). To ensure that the integrity of evidence is preserved, Sections shall provide their staff with detailed procedures in the SWMs on maintaining the custody of the samples and exhibits during the course of examination. Subsequent handling of the test samples within Sections after registration shall be in accordance with the SWMs on "Handling of Test Samples".

Since the types/nature of the exhibits received by different Sections are different, each Section has its own SWM providing different sets of guidelines. These guidelines include the assignment of cases, and the procedures for receiving, storage, examination, returning and transferring of the exhibits.

4.22 Most of the samples received by the AASD and part of the samples received by the FSD are routine samples. After completion of cases, the GL will dispose of them within a designated period of time unless requested otherwise by the user B/Ds. The procedures for disposal of the exhibits are separately stipulated in different SWMs as different samples require different treatments. For the formal samples received by the AASD, the GL did not keep any information on the exhibit return dates in the computer system. They only keep it in manual form by marking on the file. The AASD could not provide a full database on the return dates of the exhibits.

4.23 On the other hand, most of the samples received by the FSD and some of the samples received by the AASD are formal exhibits used for prosecution purposes. Such exhibits are required to be returned to the user B/Ds. The reporting officers of these Sections will normally only return the exhibits directly to the user B/Ds if there is urgency or if the case involves a large number of exhibits. Otherwise, in most cases, the reporting officer concerned will deliver the case file and exhibits for a case in person to the Forensic Counter Exhibit Officer who shall take immediate possession of the exhibits. The exhibits and the reports are ready for collection by the user B/Ds at the Forensic Counter.

4.24 Audit took 28 July 2014 as the cut-off date and checked the completion dates of the files (together with the exhibits pending collection by the user B/Ds) at the Forensic Counter and calculated the number of working days between the cut-off date and the report completion date. Audit found that 32% of the cases with reports and/or exhibits had not been collected for over 3 months after the completion date (including 14% over 1 year). Two of the cases had been completed some four years ago but were still not yet collected by the user B/Ds. Audit noted that there were no stocktaking requirements stipulated in the QAP, SOPs and SWMs for samples/exhibits, nor were there any guidelines for handling exhibits that have remained uncollected by user B/Ds for a long period of time.

4.25 Audit examined the time elapsed before the user B/Ds collected the exhibits in the period 2009 to July 2014 by analysing the number of working days between the exhibit collection dates and the report completion dates. The total number of cases with exhibits collected during the period was 127,523. In 809 cases, the exhibits were collected before the cases were completed. Audit found that out of 73,094 cases with return dates provided, most (about 98%) of the exhibits were collected within 3 months after the completion of the reports. However, there were 53,620 cases (i.e. 42% of a total of 127,523 cases) in which no such information was readily available in the computer system. Also, there were 56 cases in which the exhibits were collected over one year after the reports were completed. As such, the GL may need extra storage space/facilities to keep these long-outstanding exhibits. Audit considers that the GL needs to take measures to enhance the management of reports/exhibits pending collection by user B/Ds.

## Audit recommendations

4.26 Audit has *recommended* that the Government Chemist should take measures to enhance the GL's management of reports/exhibits pending collection by user B/Ds by, for example:

- (a) reminding and urging user B/Ds to collect the reports and the exhibits promptly;
- (b) providing more management information (e.g. the completion dates and the exhibit collection dates) for monitoring long-outstanding cases pending collection by user B/Ds; and
- (c) conducting periodic stocktakes of the exhibits at both the user Sections and the Forensic Counter in order to identify exhibits that have remained uncollected for a long period of time.

## **Response from the Administration**

4.27 The Government Chemist agrees with the audit recommendations.

## Maintenance of equipment

4.28 The GL has been using the service of the Electrical and Mechanical Services Trading Fund (EMSTF) to maintain and repair its scientific equipment, and electrical, mechanical, air-conditioning and building services equipment since the establishment of the EMSTF in 1996. According to Financial Circular No. 9/99 "Untying Departments from the Services of the EMSTF" issued in June 1999, upon untying from August 2002, user departments would be free to retain the services of the EMSTF or to choose alternative service providers to meet part or all of their electrical and mechanical service needs.

4.29 Furthermore, Financial Circular No. 6/2001 "Use of Trading Fund Services" issued in August 2001 states that a Controlling Officer may choose to enter into a service agreement with a trading fund direct, without recourse to competitive bidding, if he or she is clearly satisfied that:

- (a) the trading fund is fully capable of delivering in a cost-effective manner specific services that his or her department needs; and
- (b) having regard to the circumstances of the case (such as the urgency or the special circumstances of the services required), inviting competitive bidding for the delivery of such services is not appropriate.

The Controlling Officer will be accountable for the decision on why competitive bidding is not appropriate.

#### Renewal of Service Level Agreements with the EMSTF

4.30 The GL entered into a five-year Service Level Agreement of Comprehensive Engineering Services for Government Laboratory (SLA — Note 11) with the EMSTF starting from 1 April 2001. The SLA was renewed in April 2006 and July 2011 with an intervening three-month SLA for the period April 2011 to June 2011. Details of the SLAs are shown in Table 15.

**Note 11:** An SLA between the EMSTF and a user department incorporates the technical requirements, specifications, and terms and conditions for the provision of EMSTF services.

#### Table 15

	1 April 2001 to 31 March 2006	1 April 2006 to 31 March 2011	1 April 2011 to 30 June 2011	1 July 2011 to 31 March 2016
	(First SLA)	(Second SLA)		(Third SLA)
Contract period	5 years	5 years	0.25 year	4.75 years
No. of scientific equipment (Note)	1,100	3,400	5,200	5,200
Value of scientific equipment (Note)	\$131 million	\$208 million	\$380 million	\$380 million
Contract sum	\$40.00 million	\$43.02 million	\$1.92 million	\$40.38 million

#### Details of SLAs between the EMSTF and the GL

Source: Audit analysis of GL records

- *Remarks:* The terms were agreed at the time of signing the SLA, subject to revisions arising from changes to the equipment list during the period.
- *Note:* The number and value of electrical, mechanical, air-conditioning and building services equipment were not explicitly shown in the SLA.

#### Pilot tender exercise conducted by the GL

4.31 In April 2011, the GL conducted tender exercises for nine maintenance contracts for selected items of major scientific equipment and 107 fume cupboards. Results of the tender evaluations indicated that the total contract sum for the lowest bids of the nine contracts for 93 items (out of 5,200 items of equipment in the GL) and the 107 fume cupboards would be \$7.9 million (individual contract sums ranging from \$0.15 million to \$1.92 million) and \$0.77 million a year respectively. In the event, only one of the nine maintenance contracts (annual fee of \$0.15 million for two items of scientific equipment) was awarded to a private service provider. The GL agreed with the EMSTF to undertake the maintenance services of the other eight contracts as part of the third SLA (1 July 2011 to 31 March 2016).

### Fee adjustment under the current SLA

4.32 Under the third (current) SLA (1 July 2011 to 31 March 2016), the GL would pay the EMSTF a maintenance fee of about \$40.38 million over the period. The annual baseline fee was set at \$8.5 million (\$40.38 million over 4.75 years) according to the equipment list. The baseline fee would be adjusted according to additions and deletions to the equipment list during the period. However, at the time of signing the SLA in July 2011, the equipment list was not yet finalised and the old equipment list (5,200 items with a total value of \$380 million) was adopted. It was agreed that the baseline fee would be revised when the equipment list was finalised.

4.33 In October 2012, the equipment list was finalised at \$288 million (with some 2,800 items of equipment) and the annual baseline fee was revised downwards from \$8.5 million to \$7.47 million. It was agreed between the EMSTF and the GL that the revised baseline fee should be dated back to 1 July 2012. However, Audit noted that the SLA fee was not revised until 1 April 2013, nine months after 1 July 2012. As such, the amount of SLA fee paid during the period might involve an overpayment of \$0.77 million. Audit considers that the equipment list should be finalised before the start of a new SLA as far as possible, so that the annual baseline fee can be accurately and promptly determined. Moreover, the revised SLA fee should be implemented according to the agreed timeframe.

4.34 Upon enquiry, the GL informed Audit in September 2014 that the overpayment of \$0.77 million was a result of the trim down of annual SLA baseline fee in accordance with the updated equipment list completed in October 2012. The revised fee took retrospective effect from July 2012 but was eventually implemented from April 2013. The reconciliation of arrear in payment was not implemented in 2012 because:

(a) the GL anticipated that the equipment list would be increased in the remaining contract period ending 31 March 2016. The amount of \$0.77 million could be used to offset the increase in SLA baseline fee and thus the GL would not need to seek supplementary provision in this respect as far as possible; and (b) the overpayment would be settled upon the final instalment of SLA fee that would be made prior to the expiry of the 5-year SLA period by 31 March 2016.

### Impending expiry of current SLA

4.35 The current SLA will expire on 31 March 2016. In April 2014, the GL was exploring the way forward and the strategy for the maintenance of all equipment in use. In this regard, the GL identified some major challenges, including:

- (a) in the next few years, the warranties of many items of scientific equipment would expire. The additions to the equipment list for maintenance services might increase the SLA fee substantially; and
- (b) for some scientific equipment with advanced technology, the EMSTF might not have the required expertise to provide maintenance services.

4.36 The GL decided that market tests through a tendering exercise should be carried out to see whether some of the maintenance work could be done by other service providers before the equipment list to be covered by the SLA was finalised with the EMSTF.

## Audit recommendations

- 4.37 Audit has *recommended* that the Government Chemist should:
  - (a) plan ahead for the arrangement for equipment maintenance before expiry of the current SLA by March 2016 with a view to addressing the challenges mentioned in paragraph 4.35;
  - (b) in collaboration with the EMSTF, enhance the mechanism on updating the equipment list and revision of SLA fee, and ensure that the equipment list is finalised before the start of a new SLA; and

(c) examine the SLA fee paid for the period 1 July 2012 to 31 March 2013, and take measures to recover from the EMSTF any overpayment.

## **Response from the Administration**

4.38 The Government Chemist agrees with the audit recommendations.

4.39 The Director of the Electrical and Mechanical Services agrees with the audit recommendations. He has said that:

- (a) the EMSTF is working closely with the GL to update the equipment list and revise the SLA fee through regular meetings. The EMSTF would fully support and assist the GL in enhancing the updating mechanism and preparing the updated list for SLA renewal; and
- (b) the SLA fee adjustment due to reduction in equipment items effective from July 2012 was examined and agreed between the GL and the EMSTF. It was agreed that the fee adjustment, including the overpayment for the period from 1 July 2012 to 31 March 2013, would be settled within the current SLA period ending on 31 March 2016.

## PART 5: WAY FORWARD

5.1 This PART explores the way forward for the provision of laboratory services by the GL.

## **Challenges facing the Government Laboratory**

5.2 The GL provides a broad range of analytical, advisory and forensic services to B/Ds. Given its limited resources and the wide spectrum of government services that require its support, the GL is facing great challenges to continuously improve its efficiency and cost-effectiveness in the provision of laboratory services. In particular, the frequent occurrence of emergency incidents (notably food incidents) in recent years has put great pressure on the GL in providing urgent and complex laboratory testing and advisory services to support various B/Ds in dealing with such incidents.

## Areas for improvement

5.3 The 2002 Audit Review had found that there was room for improvement in a number of areas including turnaround time of services and coordination with user B/Ds, and highlighted the need to explore the option of outsourcing the GL's routine analytical testing services to accredited laboratories. In the current review, Audit has followed up the implementation of the 2002 audit recommendations and examined the measures (including outsourcing of laboratory services) taken by the GL to improve the efficiency and effectiveness of its services to user B/Ds. Audit has identified a number of areas that call for improvement. Key areas for improvement are set out in PARTs 2 to 4.

# Government Laboratory's long-term strategic development plan

5.4 The GL recognises that there have been changes in the demand of the services in recent years, especially in the areas of food safety, public health and consumer protection. In particular, the growing number of incidents requiring urgent services in the last few years (including melamine, phthalates and

radioactivity in food products) called for not only emergency responses and round-the-clock testing services, but also development of testing methods to meet the highest possible international standards within a very short time. The GL also recognises that, under the current organisational structure and the constraints of compartmentalised locations of its laboratories, the professional exchange among staff working in the same testing discipline could not be established.

5.5 In order to better prepare for the future needs of the society and maintain its quality of services to meet the increasing unpredictable demand for laboratory services, the GL considers that a paradigm shift in its operations is needed. The GL is meanwhile reviewing its existing operations and will discuss its long-term strategic development plan with the Food and Health Bureau to better prepare the GL to face the upcoming challenges and demands in serving the community.

## Audit recommendation

5.6 Audit has *recommended* that the Government Chemist should take on board the observations and recommendations in this Audit Report in taking forward the GL's long-term strategic development plan.

## **Response from the Administration**

5.7 The Government Chemist agrees with the audit recommendation. He has said that he would implement the recommendations made in the Audit Report as appropriate.

# Services provided by the Government Laboratory

Regime	Type of service	Main user		
Food and environmental hygiene	Analytical tests for verification of compliance with the statutory standards	Centre for Food Safety under the Food and Environmental Hygiene Department		
	Support law enforcement and routine surveillance monitoring programmes	Agriculture, Fisheries and Conservation Department		
Drug safety	Support the surveillance programme	Department of Health		
	for pharmaceutical products and proprietary Chinese medicines sale in the market; control programme to	Government Logistics Department		
	facilitate the government's tendering exercises for procuring	Hospital Authority		
	pharmaceutical products	Customs and Excise Department		
Environmental protection	Management and monitoring of air and water quality; enforcement of ordinances for environmental protection	Environmental Protection Department		
Consumer protection	Scientific services covering various products (e.g. cigarettes, toys and children's products, consumer goods and dutiable commodities) and authenticity testing	Customs and Excise Department		
Public safety	Classification of dangerous goods; 24-hour emergency response service for chemical incidents	Fire Services Department		
	Monitoring of radiation level	Hong Kong Observatory		

### Appendix A (Cont'd) (para. 1.2 refers)

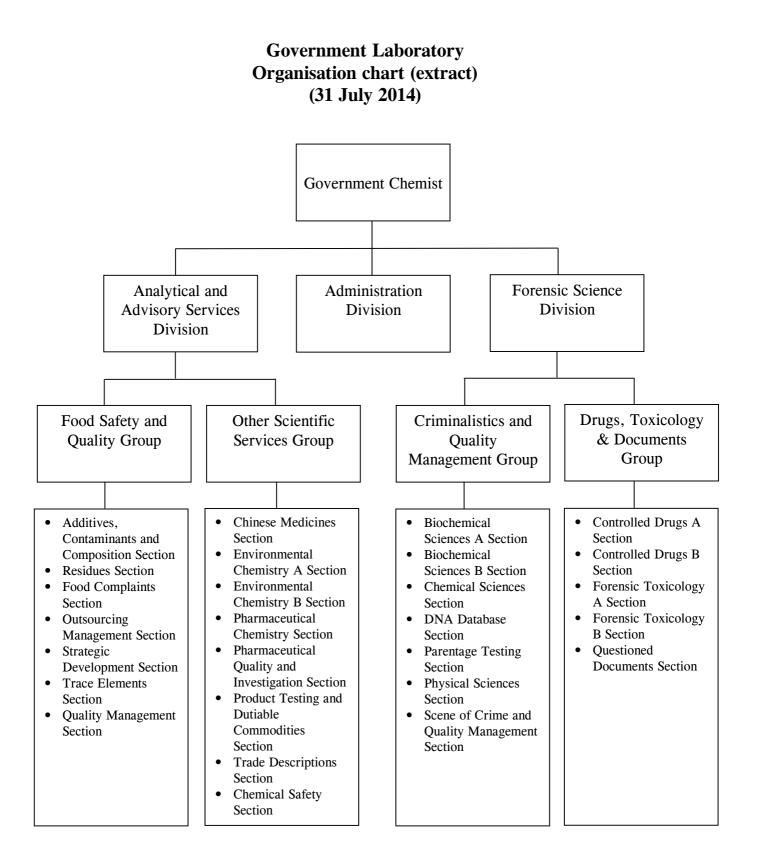
Regime	Type of service	Main user
	Surveillance of radioactive contamination of foodstuff	Food and Environmental Hygiene Department
	Technical support for the implementation of Chemical Weapons Convention	Trade and Industry Department
	weapons convention	Customs and Excise Department
24-hour scene investigation service	Scientific examination and professional evaluation of forensic evidence	Hong Kong Police Force
DNA examination	Law enforcement	Hong Kong Police Force
	Parentage testing	Immigration Department
Contact evidence	Physical examination (e.g. traffic	Hong Kong Police Force
	accident reconstruction) and trace evidence investigation	Fire Services Department
Controlled drugs	Law enforcement	Hong Kong Police Force
		Customs and Excise Department
		Department of Health
Forensic toxicology		Hong Kong Police Force
	investigation; urinalysis service under the drug use surveillance programme	Social Welfare Department
		Correctional Services Department
		Department of Health

#### Appendix A (Cont'd) (para. 1.2 refers)

Regime	Type of service	Main user
	Examination of drivers' drug/alcohol concentrations for law enforcement	Hong Kong Police Force
	Hair drug testing service (under the Healthy School Programme)	Narcotics Division of the Security Bureau
Questioned documents	Determination of authorship of questioned handwriting and signatures	Hong Kong Police Force
	Authenticity of identity documents	Immigration Department

Source: 2012 Annual Report of the GL

*Remarks:* The GL also provides technical advice to support B/Ds for amending ordinances where its scientific expertise is required. It also pursues research and development work and continues to share its findings and experiences with peers.



Source: GL records

# The number of staff and the workload of the Government Laboratory (2009 to 2013)

Year	2009	2010	2011	2012	2013
Establishment (Number of staff)	416	423	434	448	453
Number of tests performed					
Statutory testing	383,528	437,970	414,763	403,138	421,335
Advisory and investigative services	259,960	261,583	247,095	265,513	258,973
Number of statutory certificates/technical	reports iss	sued and	crime sce	nes atteno	led
Forensic science services:					
(i) statutory certificates/technical reports issued	21,708	18,202	16,932	17,372	18,752
(ii) crime scenes attended	546	432	391	413	474

Source: Controlling Officer's Reports of the GL

(paras. 1.10, 1.11, 1.13, 2.2, 2.10, 2.15, 2.19 and Appendix F refer)

# Actual compliance rates reported in the Controlling Officer's Report (2013)

		Target set	in COR	
		Turnaround time	Compliance rate	Actual compliance rate reported in COR
		(Working day)	(%)	(%)
A.	Statutory testing			•
1.	Food complaint samples (Note)	25	83%	85%
2.	Urgent samples relating to food incidents (Note)	2	100%	100%
3.	Other food samples (Note)	19	95%	98%
4.	Pharmaceuticals (quality control — Note)	14	95%	99%
5.	Pharmaceuticals (registration — Note)	30	90%	94%
6.	Chinese medicines (Note)	30	95%	97%
7.	Dangerous goods (Note)	14	95%	99%
8.	Dutiable and other commodities (Note)	10	95%	99%
9.	Non-pharmaceutical consumer goods (trade descriptions)	35	90%	96%
10.	Toys and children's products (Note)	15	95%	98%
11.	Consumer goods (Note)	35	95%	99%

(Cont'd) (paras. 1.10, 1.11, 1.13, 2.2, 2.10, 2.15, 2.19 and Appendix F refer)

		Target set	in COR	
		Turnaround time	Compliance rate	Actual compliance rate reported in COR
		(Working day)	(%)	(%)
B. A	dvisory and investigative	e services		
	ir pollution monitoring amples (Note)	20	95%	98%
	ir pollution samples for tigation purposes (Note)	18	97%	100%
	ield investigation (air ollution) samples (Note)	12	96%	100%
	Vater quality monitoring amples (Note)	20	96%	99%
m	nvironmental waste nonitoring samples Note)	27	95%	99%
sa	nvironmental waste amples for litigation urposes	12	97%	100%
	esticides formulation amples (Note)	36	93%	96%
	eepage and swimming ool water samples	10	96%	97%
	fiscellaneous - radioactivity nonitoring samples Note)	12	95%	100%
	fiscellaneous - other samples (Note)	25	90%	99%

(Cont'd) (paras. 1.10, 1.11, 1.13, 2.2, 2.10, 2.15, 2.19 and Appendix F refer)

	Target set	in COR	
	Turnaround time	Compliance rate	Actual compliance rate reported in COR
	(Working day)	(%)	(%)
C. Forensic science services			
Criminalistics and Quality Man	agement Group:		
22. DNA database	22	90%	99%
23. Biochemical sciences — non-complicated	66	90%	98%
24. Biochemical sciences — complicated	130	90%	95%
25. Parentage testing	22	90%	96%
26. Chemical sciences — trace evidence	66	90%	94 %
<ul><li>27. Physical sciences</li><li>— accident</li><li>reconstruction</li></ul>	66	90%	92%
Drugs, Toxicology and Docume	ents Group:	•	
<ul><li>28. Controlled drugs</li><li>— illicit drug seizures</li></ul>	11	90%	94%
<ul> <li>29. Controlled drugs         <ul> <li>major illicit drug</li> <li>seizures and</li> <li>manufacturing</li> </ul> </li> </ul>	44	90%	90%
<ul> <li>30. Controlled drugs</li> <li>— other illegal drug activities</li> </ul>	120	90%	94 %
31. Analytical toxicology	33	85%	92%
32. Drug urinalysis — methadone clinics	11	90%	91%

(Cont'd) (paras. 1.10, 1.11, 1.13, 2.2, 2.10, 2.15, 2.19 and Appendix F refer)

	Target set	in COR	
	Turnaround time	Compliance rate	Actual compliance rate reported in COR
	(Working day)	(%)	(%)
<ul><li>33. Drug urinalysis</li><li>— judicial-confirmation (routine)</li></ul>	22	85%	98%
<ul> <li>34. Drug urinalysis</li> <li>— judicial-confirmation (enhanced probation)</li> </ul>	5	100%	100%
35. Drug-driving	33	85%	93%
36. Drink-driving	11	90%	96%
<ul> <li>37. Questioned documents</li> <li>— handwriting</li> <li>examination</li> </ul>	66	85%	95%
38. Questioned documents — counterfeiting/ forgery	33	90%	96%
39. Questioned documents — express counterfeiting/ forgery service	1	99%	99%

Source: Audit analysis of the GL records

Note: This category has sub-categories. The quoted number of working days required for its turnaround time represents an average of reporting time for the different types of samples and test requests in its sub-categories within the category, while the target (in percentage) is the total compliance rate of the concerned samples and test requests within a particular category against their sub-categories' respective targets (which are not disclosed in the COR).

Appendix E (Note to Table 2 in para. 2.14 and Appendix F refer)

## Illustration of calculation of average target turnaround time for "Pharmaceuticals (quality control)"

		Number of submissions			Target turnaround time	Su	mmatio	n of wo	rking da	ays		
	Sub- category	Year 2009	Year 2010	Year 2011			(Working day)	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013
		A1	A2	A3	A4	A5	В	$C1 = A1 \times B$	$\begin{array}{c} C2 = \\ A2 \times B \end{array}$	$C3 = A3 \times B$	$C4 = A4 \times B$	$C5=A5 \times B$
1.	C&E	1	_	_	_	_	2	2	_	_	_	_
2.	C&E	-	_	1	_	_	5	_	_	5	_	_
3.	C&E	1	10	1	_	_	7	7	70	7	_	_
4.	C&E	1	_	_	—	—	10	10	_	_	_	_
5.	C&E	-	_	2	_	—	14	—	_	28	_	—
6.	C&E	1	_	1	_	_	20	20	_	20	-	_
7.	C&E	5	_	2	1	_	30	150	_	60	30	_
8.	C&E	-	1	_	_	_	35	_	35	_	-	_
9.	C&E	2	3	_	_	_	40	80	120	_	_	_
10.	C&E	1	_	_	—	_	45	45	_	_	_	_
11.	C&E	-	1	—	—	—	50	_	50	_	_	—
12.	C&E	31	8	3	2	_	60	1,860	480	180	120	_
13.	C&E	1	_	_	—	_	80	80	_	_	_	_
14.	C&E	49	37	45	12	_	90	4,410	3,330	4,050	1,080	_
15.	C&E	11	1	4	6	—	120	1,320	120	480	720	—
16.	C&E	4	30	28	47	_	180	720	5,400	5,040	8,460	_
17.	GSD1	-	1	_	_	_	14	_	14	_	_	—
18.	GSD1	13	4	_	1	_	30	390	120	_	30	—
19.	GSD1		3	6	14	_	35		105	210	490	_
20.	HA	-	1	_	_	_	35	_	35	_	_	_
21.	HA	43	79	95	62	62	45	1,935	3,555	4,275	2,790	2,790
22.	HA	4	_	—	1	_	90	360	_	_	90	_

#### Appendix E

(Cont'd) (Note to Table 2 in para. 2.14 and Appendix F refer)

		Nı	Number of submissions			Target turnaround	Su	n of wo	working days			
	Sub- category	Year 2009	Year 2010	Year 2011			time (Working day)	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013
		A1	A2	A3	A4	A5	В	$C1 = A1 \times B$	$C2 = A2 \times B$	$C3 = A3 \times B$	$C4 = A4 \times B$	$C5=A5 \times B$
23.	PM1	51	58	51	59	4	8	408	464	408	472	32
24.	PM1	36	28	37	38	42	14	504	392	518	532	588
25.	PM1	_	_	1	_	—	35	-	—	35	_	_
26.	PM2	_	_	5	_	_	8	_	_	40	_	-
27.	PM2	1	_	—	_	_	14	14	—	—	_	_
28.	PM2	520	472	519	544	576	35	18,200	16,520	18,165	19,040	20,160
29.	PM3	_	_	_	_	50	8	_	_	_	_	400
30.	PP	_	204	56	5	_	15	_	3,060	840	75	-
31.	PP	3	_	51	10	_	30	90	_	1,530	300	_
32.	PP	_	_	6	_	_	60	_	_	360	_	_
33.	PP	_	_	1	_	_	150	_	_	150	_	_
34.	PP	42	97	81	28	_	180	7,560	17,460	14,580	5,040	_
	Total	821	1,038	996	830	734		38,165	51,330	50,981	39,269	23,970
	Average target turnaround time							46	49	51	47	33

Legend: C&E Customs and Excise Department

- GSD1 Government Logistics Department
- HA Hospital Authority
- PM1 Pharmaceutical manufactory single
- PM2 Pharmaceutical manufactory multiple
- PM3 Pharmaceutical manufactory others
- PP Certification of pharmaceutical product

Source: Audit analysis of GL records

Appendix F (para. 2.15, Appendices D and E refer)

#### Case 1

## Audit analysis of the COR performance information for testing of "Pharmaceuticals (quality control)"

1. This category includes routine analytical works relating to the quality control of pharmaceutical preparations being manufactured and/or procured by the Department of Health and the Hospital Authority (HA), and its performance information reported in the COR is a composite of the performance results of its 34 underlying sub-categories (see Appendix E).

**COR targets: turnaround time averaging 14 working days and compliance rate of 95%** (see para. 2.10 and Item 4 at Appendix D)

2. According to the COR, the GL set a turnaround time averaging 14 working days and a target that 95% of test requests would be completed within the respective target turnaround time specified for each of its 34 sub-categories as applicable. In 2013, 5 of the sub-categories received a total of 734 test requests from their user B/Ds (see also Appendix E). The GL reported that it achieved actual compliance of 99%, with a target turnaround time averaging 14 working days.

#### Not all test requests included for calculating compliance rate

3. The GL provided the 2013 data for audit analysis in August 2014. Audit reperformed the calculation of the compliance rates by comparing the actual turnaround time of each submission with its target turnaround time of the respective sub-category, and found that the compliance rate was 94%. This was different from that reported of 99% in the COR. In September 2014, Audit made an enquiry with the GL about the reasons for the discrepancy. The GL informed Audit that some sub-categories (test requests from the C&ED and HA) had been excluded from calculating the compliance rates. According to the GL, the testing work for the HA, and similarly some testing work which had been agreed with the user B/Ds, had not been included for calculation because they were testing work of lower priority, and had been taken up on the condition that the GL's main functions were not affected. Audit re-calculated the compliance rate taking into account GL's explanations and found that it matched with the compliance rate published in the COR. Details are given below:

Appendix F (Cont'd) (para. 2.15, Appendices D and E refer)

	2013 data for the category			
	Before exclusion	After exclusion of some data		
Number of sub-categories involved	34	15		
Range of target turnaround time (working days)	2 to 180	8 to 180		
Number of cases included for calculation	734	672		
Range of target turnaround time (working days) for test sub-categories	8 to 45	8 to 35		
Average actual turnaround time (working days)	13	10		
Compliance rate calculated by Audit (A)	94%	99%		
Compliance rate published in COR (B)	99%	99%		
Difference (B)-(A)	5%	0%		

4. Audit analysed the actual turnaround time of the 62 (734 - 672) cases relating to the HA's sub-category (i.e. Item 21 at Appendix E with 45 working days as the target sub-category turnaround time) which had been excluded from the performance measurement calculation. Details are given below:

	HA sub-category with target turnaround time of 45 working days
Number of cases	62
Cases completed:	
within 14 working days (COR's average)	3 (5%)
within the sub-category's target turnaround time	35 (57%)
average of actual turnaround time for this sub-category	43 working days
Actual turnaround time	Number of cases
1 to 5 working days	0 (0%)
6 to 10 working days	2 (3%)
11 to 14 working days	1 (2%)
15 to 20 working days	5 (8%)
21 to 30 working days	11 (18%)
31 to 45 working days	16 (26%)
46 to 60 working days	13 (21%) 43%
Over 61 working days	14 (22%) 5 43 %

Appendix F (Cont'd) (para. 2.15, Appendices D and E refer)

5. It can be seen from paragraph 4 above that about half of the cases (43%) could not be completed within the target turnaround time of 45 working days. Furthermore, Audit could not find any written justification and authority for the exclusion of the cases from the performance measurement calculation. Upon enquiry, the GL informed Audit in October 2014 that all analytical examinations for items from subvented organisations and similar bodies, including the HA, were charged on a cost-recovery basis commencing 2000. The Government Chemist might refuse any item for analytical examinations requested by such bodies. The GL therefore considered that "written justification and authority" for the exclusion of the services to the HA from the performance measurement calculation was not necessary.

#### The target turnaround times of the sub-categories were generally much higher than the actual turnaround time

6. Audit further analysed the 2013 information of 576 cases relating to the largest sub-category (i.e. Item 28 at Appendix E with 35 working days as the target sub-category turnaround time).

	Sub-category with target turnaround time of 35 working days
Number of cases	576
Cases completed:	
within 14 working days (COR's average)	494 (86%)
within the sub-category's target turnaround time	576 (100%)
average of actual turnaround time for this sub-category	10 working days
Actual turnaround time	Number of cases
1 to 5 working days	101 (17%)
6 to 10 working days	223 (39%)
11 to 14 working days	170 (30%)
15 to 20 working days	67 (11%)
21 to 30 working days	15 (3%)

Appendix F (Cont'd) (para. 2.15, Appendices D and E refer)

7. It can be seen from paragraph 6 above that the actual case turnaround time was much shorter than the target 35 working days. The sub-category reported a compliance rate of 100% using the 35 working days as the turnaround compliance measure. In fact, all cases were completed within 30 working days and a large majority of them (97%) were completed within 20 working days. However, if 14 working days as reported in the COR had been used as the measure, the compliance rate would have dropped to 86%. Nevertheless, it seems that there is scope for the GL to shorten the target turnaround time for the sub-category to a level of less than 35 working days.

#### Turnaround time stated in the COR not used to measure the compliance rate

8. Audit noted that what was stated as average turnaround time in the COR (average of 14 working days) was not what was used by the GL to measure the compliance rate. As can be seen from Appendix E, there were 734 test requests involving 5 sub-categories (Items 21, 23, 24, 28 and 29) in 2013. However, the target turnaround times used to measure compliance of these 5 sub-categories' turnaround time were 45, 8, 14, 35 and 8 working days respectively, and not the stated turnaround time of 14 working days mentioned in the COR (see Appendix E). The compliance rates of these 5 sub-categories were 57%, 75%, 90%, 100% and 96% respectively.

9. Upon Audit's enquiry, the GL explained that the stated turnaround time of 14 working days actually represented the average of the turnaround times of the 734 items, which had achieved target turnaround times ranging from 8 to 45 working days. While noting that the GL did not use the 14 working days to measure the compliance rate, Audit used it as a benchmark to reperform the measurement of compliance rate of this category. Audit found that had 14 working days been used as the benchmark to measure the turnaround time of all 734 items, the actual compliance rate would have been 80%, not the 99% reported (see Item 4 at Appendix D). Even if the HA sub-category had been excluded, the actual compliance rate would have been 87%.

#### Audit comments

10. Audit considers that the GL should qualify its performance targets if it intends to exclude certain classes of testing work from calculating the performance result. The GL should set down clearly the criteria of testing work that would be excluded from calculation. Audit also considers that the GL should critically review and monitor the performance target achievement and set reasonable target turnaround times for sub-categories to further improve its service provision. Additionally, the GL should consider revising the description of the performance indicator to make it clear that the average turnaround time of 14 working days is not used to measure the compliance rate of the test items, and also consider disclosing the range of respective target turnaround times (8 to 45 working days) actually used to measure the compliance rate.

Source: Audit analysis of GL records

## Appendix G

# Acronyms and abbreviations

AASD	Analytical and Advisory Services Division
Audit	Audit Commission
AWIs	Areas worth improvement
B/Ds	Bureaux and departments
COR	Controlling Officer's Report
C&ED	Customs and Excise Department
DECC	Departmental Emergency Coordinating Centre
EMSTF	Electrical and Mechanical Services Trading Fund
ESIMS	Extended Sample Information Management System
EU	Efficiency Unit
FAPAS	Food Analysis Performance Assessment Scheme
FEHD	Food and Environmental Hygiene Department
FSD	Forensic Science Division
GCC	Government Chemist's certificate
GL	Government Laboratory
НА	Hospital Authority
HKAS	Hong Kong Accreditation Service
HKPF	Hong Kong Police Force
HOKLAS	Hong Kong Laboratory Accreditation Scheme

# Appendix G (Cont'd)

IEC	International Electrotechnical Commission
IIEB	Internal Ordering, Inventory Keeping, External Purchases and Budgetary Control System
ISO	International Organisation for Standardisation
MOU	Memorandum of Understanding
NCs	Non-conformities
NFA	No further action
ОМ	Outsourcing Management
PIR	Post-implementation review
РТ	Proficiency testing
QA	Quality Assurance
QAP	Quality Assurance Protocol
QC	Quality check
SIMS	Sample Information Management System
SLA	Service Level Agreement of Comprehensive Engineering Services
SLTs	Science Laboratory Technologists
SMMs	Senior Management Meetings
SOPs	Standard Operating Procedures
SPRs	Stores and Procurement Regulations
SWMs	Sectional Work Manuals