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**Paper for the House Committee meeting on 27 November 2020**

**Report of the Subcommittee on Medical Laboratory Technologists  
(Special Exemptions) Regulation**

**Purpose**

This paper reports on the deliberations of the Subcommittee on Medical Laboratory Technologists (Special Exemptions) Regulation ("the Subcommittee").

**Medical Laboratory Technologists (Special Exemptions) Regulation**

2. Under section 20(2) of the Supplementary Medical Professions Ordinance (Cap. 359) ("the SMP Ordinance"), a company (registered under the Companies Ordinance (Cap. 622) or the Companies Ordinance (Cap. 32) ("registered company") as in force at the time of registration) may carry on the business of practising the profession of medical laboratory technologist if, among others, all persons practising that profession who are employed by the company are registered in respect of that profession. Under section 20(4) of the SMP Ordinance, contravention of the relevant requirement by a registered company is an offence and every director and manager thereof commits the like offence.<sup>1</sup> Further, under section 21(1) of the SMP Ordinance, it is an offence for a person to practise the profession of medical laboratory technologist without being registered.<sup>2</sup> Under section 29(1A)(d) of the SMP Ordinance, the Secretary for Food and Health ("SFH") may by regulation exempt any specified class of persons from all or any of the provisions of the Ordinance.

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<sup>1</sup> Under section 27(e) of the SMP Ordinance, a person who commits an offence under section 20(4) of the SMP Ordinance is liable on conviction to a fine at level 2 (i.e. \$5,000) and imprisonment for 6 months.

<sup>2</sup> Under section 27(f) of the SMP Ordinance, a person who commits an offence under section 21(1) or 21(2) of the SMP Ordinance is liable on conviction to a fine at level 2 (i.e. \$5,000) and imprisonment for 6 months.

3. The Medical Laboratory Technologists (Special Exemptions) Regulation (L.N. 153 of 2020) ("the Regulation") is made by SFH under section 29(1A) of the SMP Ordinance to exempt (a) a member of the National accredited laboratory testing personnel arranged by the National Health Commission of the People's Republic of China ("specified person") to conduct nucleic acid tests for detecting coronavirus disease 2019 ("COVID-19") ("specified tests") in Hong Kong for the Government from section 21(1) of the SMP Ordinance regarding the offence for non-compliance with the registration requirement in relation to the profession of medical laboratory technologist; and (b) a registered company which carries on the business of practising the profession of medical laboratory technologist ("specified company") from section 20 of the SMP Ordinance in respect of the profession of medical laboratory technologist for employing a specified person to conduct specified tests for the Government.

4. The Regulation was published in the Gazette on 7 August 2020. It came into operation on 8 August 2020 and expired at midnight on 7 October 2020. The Regulation was tabled before the Legislative Council at its meeting of 14 October 2020 and is subject to negative vetting procedure.

### **The Subcommittee**

5. At the House Committee meeting on 16 October 2020, Members agreed to form a Subcommittee to study the Regulation. Hon WONG Ting-kwong was elected Chairman of the Subcommittee.<sup>3</sup> The membership list of the Subcommittee is in the **Appendix**.

6. The Subcommittee has held two meetings with the Administration. The Subcommittee has received oral representations from two deputations, namely Hong Kong Biomedical Scientists Association and Hong Kong Institute of Medical Laboratory at one of these meetings.

7. To allow more time for it to study the Regulation, the Subcommittee agreed that a motion should be moved at the Council meeting of 11 November 2020 to extend the scrutiny period of the Regulation to the Council meeting of 2 December 2020. However, the motion was not dealt with before adjournment of the said Council meeting. As such, the period for amending the Regulation expired at the Council meeting of 11 November 2020.

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<sup>3</sup> Prof Hon Joseph LEE was the Chairman of the Subcommittee from 6 to 10 November 2020.

## **Deliberations of the Subcommittee**

8. While members in general have no objection to the Regulation, they have expressed concerns on various issues during the course of scrutiny. The major deliberations of the Subcommittee are set out in the ensuing paragraphs.

### Justifications for granting the exemptions

9. Hong Kong's third wave of COVID-19 epidemic started in early July 2020, with an upsurge in locally infected cases, many with yet unknown sources. While there was an urgent need to carry out large-scale COVID-19 testing as early as possible in the shortest possible time to protect public health amidst the third wave epidemic, the Administration noted that Hong Kong did not have sufficient laboratory testing personnel with adequate training and experience to perform COVID-19 testing under the Universal Community Testing Programme ("UCTP")<sup>4</sup>.

10. Members note that a total of about 1 783 000 specimens had been collected under the 14-day UCTP for the specified tests. A total of 32 new confirmed cases were identified, among which 13 were asymptomatic and 20 were local cases with unknown sources of infection. Members including Mr CHAN Han-pan, Ms Elizabeth QUAT and Mr Vincent CHENG have expressed gratitude to the Central Government for deploying rapidly a nucleic acid test support team consisting of some 570 members and providing necessary equipment to enhance the COVID-19 testing capability of Hong Kong in such a short period of time, thus enabling the launch of UCTP which helped the identification of asymptomatic patients in the community to prevent further transmission of the virus for better control of the third wave of the epidemic. Some other members including Dr Helena WONG and Mr SHIU Ka-chun have enquired about the respective daily COVID-19 testing capacity of the public and private sectors in early August 2020 to justify the need for granting the exemptions under the Regulation.

11. The Administration has advised that in early August 2020, the public sector (including the Public Health Laboratory Services Branch of the Department of Health ("DH"), the Hospital Authority ("HA") and the two universities (i.e. The Chinese University of Hong Kong ("CUHK") and The University of Hong Kong

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<sup>4</sup> UCTP was implemented from 1 to 14 September 2020 to provide a one-off free COVID-19 testing service for all Hong Kong residents (except for children under six years old and people not suitable for the test) in order to identify as early as possible asymptomatic COVID-19 patients in the community and achieve the target of early identification, early isolation and early treatment to cut the community transmission chain.

("HKU")) had a regular capacity of 3 280 samples per day.<sup>5</sup> By staff deployment and overtime work, together with suspension or reduction of other testing services, the respective daily maximum surge capacity of DH and HA was 1 320 and 1 500 samples at that time, making the maximum daily capacity of the public sector reached 6 100 samples per day. As regards the private sector, the overall daily testing capacity of private laboratories which had obtained relevant accreditation in Hong Kong was around 40 000 in early August 2020. Separately, in consultation with the medical laboratory sector on whether the existing manpower of medical laboratory technologists in Hong Kong could support the implementation of UCTP given the scale of the testing within a very short period of time involved, the Administration considered it necessary to allow the specified persons to come to Hong Kong to assist in performing the specified tests under UCTP for a limited period of time so as to meet the impending need to carry out large-scale testing in the shortest possible time to protect public health.

12. Noting that the virus may be more active in autumn and winter and the number of local confirmed cases has shown an increasing trend since November 2020, members have expressed concern about the latest COVID-19 testing capacity of Hong Kong and whether another round of exemptions would be warranted in the face of a possible rebound of the epidemic situation. Ms Elizabeth QUAT goes further to suggest that the Administration should implement compulsory population-wide testing for COVID-19 with a view to breaking the virus transmission chain in the community and achieving "zero infection" so that cross-border travel without the need for compulsory quarantine could be resumed at an early date through mutual recognition of health codes.

13. The Administration has assured members that the testing capacity in Hong Kong has been enhanced significantly in the past months. With the commissioning of the laboratory of DH in the Hong Kong Children's Hospital and the new laboratories of CUHK and HKU in late July and early September 2020 respectively, the testing volume that can be handled by public testing services on a regular basis has increased to over 7 000 per day. In addition, the public sector will procure testing services from local private laboratories when necessary to further enhance public testing capacity. With the efforts of the industry and the facilitation by the Administration, the overall daily testing capacity of private laboratories which have obtained relevant accreditation in Hong Kong has increased significantly to close to 100 000 in mid-November 2020. The cost for the testing services provided by private laboratories has also dropped considerably. The Administration has further advised that to enhance and broaden surveillance at the community level, it has integrated and regularized the

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<sup>5</sup> The respective regular daily testing capacity of DH, HA, CUHK (stool samples) and HKU was 1 980, 1 000, 100 and 200 in early August 2020.

Targeted Group Testing Scheme as part of sentinel surveillance and as a main tier of the Enhanced Laboratory Surveillance Programme of the Centre for Health Protection of DH. The Scheme not only helps with "early identification, early isolation and early treatment", but also provides data for reference for the overall assessment of the epidemic situation.

#### Qualifications of the specified persons

14. Members note that for persons who would like to register as a medical laboratory technologist in Hong Kong, they should hold the qualifications as prescribed in section 4 of the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359A) ("the MLT Regulations").<sup>6</sup> For applicants holding other qualifications, their applications will be considered on individual merits. Dr Helena WONG has enquired about the qualifications held by the specified persons.

15. The Administration has advised that the specified persons are National accredited laboratory testing personnel, who possess adequate training and experience on COVID-19 nucleic acid testing, arranged by the National Health Commission of the Central Government to conduct specified tests in Hong Kong. Given the Mainland and Hong Kong have their respective registration requirements and regulatory mechanism, it would not be possible to make a direct comparison.

16. Noting that the specified persons are exempted from local registration and hence, not bound by the Code of Practice for Registered Medical Laboratory Technologists promulgated by the Medical Laboratory Technologists Board, Dr Helena WONG and Mr SHIU Ka-chun have enquired about the mechanisms put in place by the Administration to deal with complaints, if any, against the

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<sup>6</sup> According to section 4 of the MLT Regulations, a person shall be qualified for registration if the person (a) holds a Diploma in Medical Laboratory Science issued by the Hong Kong Polytechnic; (b) holds an Ordinary Certificate in Medical Laboratory Technology issued by the Department of Extra-mural Studies of HKU; (c) holds a Certificate of Competency in Medical Laboratory Technology issued by the Medical and Health Department of the Hong Kong Government prior to 1982; (d) holds a Higher Certificate in Medical Laboratory Technology issued by the Department of Extra-mural Studies of HKU; (e) holds a Higher Diploma in Medical Laboratory Science issued by the Hong Kong Polytechnic or The Hong Kong Polytechnic University ("PolyU"); (f) holds a Bachelor of Science degree in Biomedical Science awarded by the Hong Kong Polytechnic or PolyU; (g) holds a Bachelor of Science degree in Medical Laboratory Science awarded by PolyU; or (h) holds a certificate from the Medical Laboratory Technologists Board that he has passed an examination relating to the profession of a medical laboratory technologist conducted under section 15A of the SMP Ordinance for the purposes of section 12(1)(a) of the SMP Ordinance.

specified persons in relation to their misconduct or neglect in any professional respect. The Administration has advised that no complaint against the specified persons had been received. Should there be any complaint in this regard, it would report such cases to the National Health Commission.

The exemption granted for a specified company

17. The Legal Adviser to the Subcommittee has drawn members' attention that under section 21(2) of the SMP Ordinance, any person who employs any other person to practise a profession to which the SMP Ordinance relates when the second-mentioned person is not registered in respect of that profession commits an offence. It appears that a specified company which employs specified persons (who are not registered medical laboratory technologists) would commit an offence under section 21(2) of the SMP Ordinance notwithstanding the exemption from the application of section 20 of the SMP Ordinance<sup>7</sup> under section 2(2) of the Regulation.

18. According to the Administration, the offence of a corporation, including a company employing an unregistered person to practise the profession of medical laboratory technologist has already been covered in section 20(4) of the SMP Ordinance. It is unlikely in such circumstances that the offence of employing an unregistered person to practise the profession of medical laboratory technologists will again cover a corporation or company. It is also noted that in the exemption under Schedule 4 to the MLT Regulations, an institution carried on by a corporation is only exempted from section 20 but not from section 21(2) of the SMP Ordinance and the only entity who is exempted from section 21(2) is a natural person, namely a veterinary surgeon. This further affirms that a corporation or company is not covered in section 21(2) of the SMP Ordinance. Hence, the Administration considers that it is not necessary to exempt a specified company from the application of section 21(2) of the SMP Ordinance.

Service quality of local private COVID-19 nucleic acid testing institutions

19. Dr Pierre CHAN has expressed concern about the service quality of the local private COVID-19 nucleic acid testing institutions. He has pointed out that while the registration and professional conduct of medical laboratory technologists are subject to regulation under the MLT Regulations, medical testing laboratories

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<sup>7</sup> Section 20(2) of the SMP Ordinance provides that a company may carry on the business of practising the profession of medical laboratory technologist if, among others, all persons practising the profession of medical laboratory technologist who are employed by the company are registered in respect of that profession. A corporation which carries on the business of practising the profession of medical laboratory technologist other than in compliance with section 20(2) commits an offence under section 20(4) of the SMP Ordinance.

are not being regulated under the Private Healthcare Facilities Ordinance (Cap. 633).<sup>8</sup> These premises can, on a voluntary basis, seek accreditation under the Hong Kong Laboratory Accreditation Scheme ("HOKLAS") operated by the Hong Kong Accreditation Service ("HKAS").

20. The Administration has informed the Subcommittee that in order to obtain accreditation under HOKLAS, medical testing laboratory shall be a legal entity in Hong Kong; meet the standard requirements of ISO 15189:2012 (i.e. Medical laboratories - Requirements for quality and competence) and relevant supplementary requirements stipulated by HKAS; and fulfill the general regulations related to the administration of accreditation schemes by HKAS. It should be noted that in order for the relevant accreditation to be recognized by the Administration for the purpose of the Laboratory Recognition Scheme, local COVID-19 nucleic acid testing institutions must have attained medical laboratory accreditation from the College of American Pathologists, HKAS or its Mutual Recognition Arrangements partners; and certification of SARS-CoV-2 Quality Assurance Programme from the Centre for Health Protection of DH or Proficiency Testing Providers accredited by HKAS or its Mutual Recognition Arrangements partners.

21. Mrs Regina IP notes that the COVID-19 nucleic acid test can only be carried out under the referral of a registered medical practitioner otherwise the medical laboratory technologist involved may be deemed to have contravened the Code of Practice for Registered Medical Laboratory Technologists. Given that the cost for the testing services varies among the private laboratories, she holds the view that it would be more desirable if patients could have freedom to choose the private laboratories for testing if they so wished.

#### Sampling methods for COVID-19 virus testing

22. Members note that under UCTP, specimen were collected through combined nasal and throat swabs by trained medical or healthcare staff. There is an enquiry as to the reason why the specimen collection method of deep throat saliva, which has been employed by the Public Health Laboratory Services Branch of DH and HA, for the reverse transcription polymerase chain reaction nucleic acid test was not employed under UCTP. The Administration has explained that the two methods are generally similar in accuracy and sensitivity, and could both effectively identify COVID-19 cases. Scientifically, there is no single testing technique or specimen collection method that can ensure complete accuracy. The

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<sup>8</sup> The private healthcare facilities being regulated under the Private Healthcare Facilities Ordinance include hospitals, day procedure centres, clinics and health services establishments.

Administration would continue to review the suitability of different testing techniques and specimen collection methods.

### Manpower planning for the profession of medical laboratory technologist

23. Members note that PolyU, as the only institution offering University Grants Committee ("UGC")-funded degree programme in the field of medical laboratory science, has increased the number of UGC-funded First-Year-First-Degree training places in medical laboratory science from 32 in the 2011-2012 academic year to 54 in the 2020-2021 academic year. Separately, the HKU School of Professional and Continuing Education runs a higher certificate course in medical laboratory science, providing about 70 training places on an alternate-year basis. Tung Wah College also operates a self-financing degree programme in medical laboratory science, which is subsidized by the Government under the Study Subsidy Scheme for Designated Professions/Sectors. The number of subsidized training places for the 2019-2020 cohort is 45.

24. Drawing on the experience of using virus testing as a control measure to combat COVID-19, members are of the view that having a larger pool of qualified medical laboratory technologists is detrimental to the provision of testing services necessary for the maintenance of public health in Hong Kong. They have urged the Administration to plan ahead in this regard, as the findings of the Strategic Review on Healthcare Manpower Planning and Professional Development ("the Strategic Review") promulgated in 2017 had revealed that there would be a slight shortage (but close to equilibrium) of medical laboratory technologists in the short to medium term. The Administration has advised that based on the recommendations of the Strategic Review, it will update the manpower projection for healthcare professionals (including medical laboratory technologists) once every three years in step with the UGC triennium. A new round of manpower projection exercise is now in full swing, and the result is expected to be ready by end 2020 or early 2021. Subject to the findings of the manpower projection, the Government will consider whether to further increase the training places in medical laboratory science in the next UGC triennium.

### **Recommendation**

25. The Subcommittee raises no objection and will not propose amendments to the Regulation.



**Advice sought**

26. Members are invited to note the deliberations of the Subcommittee.

Council Business Division 2  
Legislative Council Secretariat  
26 November 2020

**Subcommittee on Medical Laboratory Technologists  
(Special Exemptions) Regulation**

**Membership list\***

<b>Chairman</b>	Hon WONG Ting-kwong, GBS, JP
<b>Members</b>	Hon Mrs Regina IP LAU Suk-ye, GBS, JP Hon CHAN Han-pan, BBS, JP Hon Elizabeth QUAT, BBS, JP Dr Hon Pierre CHAN Hon CHEUNG Kwok-kwan, JP Hon Vincent CHENG Wing-shun, MH, JP
	(Total : 7 members)
<b>Clerk</b>	Ms Maisie LAM
<b>Legal Adviser</b>	Ms Vanessa CHENG
<b>Date</b>	19 November 2020

\* Changes in membership are set out in Annex to Appendix

## Annex to Appendix

### Subcommittee on Medical Laboratory Technologists (Special Exemptions) Regulation

#### Changes in membership

<b>Member</b>	<b>Relevant date</b>
Hon SHIU Ka-chun	Up to 9 November 2020
Prof Hon Joseph LEE, SBS, JP (Chairman)	Up to 10 November 2020
Hon IP Kin-yuen	Up to 10 November 2020
Hon Jeremy TAM Man-ho	Up to 11 November 2020
Dr Hon Helena WONG Pik-wan	Up to 12 November 2020
Hon James TO Kun-sun	Up to 12 November 2020
Hon KWONG Chun-yu	Up to 12 November 2020
Dr Hon Fernando CHEUNG Chiu-hung	Up to 18 November 2020

According to the announcement made by the Hong Kong Special Administrative Region Government on 11 November 2020 pursuant to the Decision of the Standing Committee of the National People's Congress on Issues Relating to the Qualification of the Members of the Legislative Council of the Hong Kong Special Administrative Region, Kenneth LEUNG, KWOK Ka-ki, Dennis KWOK Wing-hang and Alvin YEUNG were disqualified from being a member of the Legislative Council on 30 July 2020.