Agenda for the 18th meeting of the Biosafety Committee of the University of Hong Kong. (A sub-committee of the Safety Health and Environment Committee).

To be held on Thursday, December 14th 2017, 11.30 a.m. Room 412 at Professorial Block, Queen Mary Hospital.

1. Minutes of the 17th meeting of the Biosafety Committee (October 20th 2016)
The minutes of the previous meeting of the Biosafety Committee were circulated in March 2017 and members approved them by e-mail. For completeness they are attached as Appendix 1.

2. Matters arising from the minutes of the 17th meeting (action points etc.)
The secretary arranged for the minutes to be uploaded to the safety office website (please see: - http://www.safety.hku.hk/homepage/BCom.html). The updated RA3 form and retrovirus guidance were circulated via e-mail to a general list of relevant departments and staff (action under agenda point 5). The updated biosafety policy was endorsed by SHEC at its meeting on December 6th 2016 (action under agenda point 6). The secretary has produced a document (see below at agenda point 5) which includes details of the requirements in Hong Kong for import and export licenses in respect of biological samples (action under agenda point 7).

3. Official status of the Biosafety Committee
The committee should note that the University Council has approved the restructuring of the Safety, Health and Environment Committee (SHEC) and the University Health Services Committee (UHSC) into a single Committee on Health, Safety and Well-Being. The restructuring involves the disestablishment of both SHEC and UHSC.

As the Biosafety Committee was formally designated a specialist sub-committee which reported to SHEC it is expected that this status will be transferred formally to the new committee when it is formed. However the new committee may decide on different supervisory arrangements.

Members are asked for their views on the current arrangements and what sort of submission should be made to the new Committee on Health, Safety and Well-Being. Would there be a better fit if the committee were supervised or responsible to other University post holders? For example the Research Deans of the Faculties of Science and Medicine might be able to better ensure policy is followed than the central committee.

4. Introductory course in biosafety
The next introductory course in biological safety will be held from 2-5PM on January 15th 2018 in the Mrs Chen Yang Foo Oi Telemedicine Centre, 2/F William M W Mong Block, Li Ka Shing Faculty of Medicine, 21 Sassoon Road. If members are aware of staff or students who might benefit, please bring it to their attention. The slides used in a previous session have been uploaded to the Safety Office website and links to the courses files can be found on http://www.safety.hku.hk/homepage/bio.html.

5. The safe transport of infectious materials and import/export requirements for Hong Kong.

In response to a number of requests for guidance on import and export requirements in Hong Kong a draft policy on transport of infectious materials and international import/export has been produced. It is attached as Appendix 2.

The secretary would appreciate comments and suggestions on how to improve the document. The draft has deliberately avoided the full detail of all the UN labelling and packaging requirements in order to simplify the document and encourage the use of specialist couriers. Do members think it would be useful to include this detail?

6. Risk assessment worksheet for clinical samples

In response to requests from several departments the secretary has developed a worksheet to assist users identify the risks associated with handling clinical samples. Some guidance on the important issues around controlling these risks is also included along with reference to other guidance on clinical samples previously approved by the committee. This worksheet is attached to the agenda as Appendix 3.

The secretary would appreciate comments and suggestions on how to improve the worksheet. In particular question 6 is from the original source worksheet and probably doesn't reflect practice in HKU. Alternative question/s would be welcome.

7. Review of current Biosafety documentation

It is generally considered to be good practice to include approval and review dates on guidance documents. Appendix 4 contains a table of the current biosafety guidance and policy etc. along with the dates when they were first approved (including those presented today) and if and when any subsequent update was approved. As can be seen from the table many of the review dates have been missed.

The secretary has had a brief look through those documents overdue for review and would not make many alterations to what has been approved. How would members suggest dealing with this situation and reviewing the documentation? Is there a case to be made for leaving off a date for review if the approval date is included?

Are the committee aware of any other areas where guidance would be helpful?

8. Accident reporting at BSL3 for scheduled agents

Appendix 5a details an accident that occurred in the BSL3 on the 5th floor of the FMB building on Aug 2nd 2017 which involved a minor spill of MERS.

CAP599A Part 8 Para 43 states that the Laboratory shall notify the Director of Health in "cases of leakage of scheduled infectious agents".

(1)If it comes to the knowledge of the owner or the person in charge of a laboratory that there is a leakage of a scheduled infectious agent in the laboratory that may pose a public health risk, the owner or that person shall notify the Director immediately.

(2)The owner or the person in charge of the laboratory shall give to the Director any information that is required by a health officer to facilitate the investigation of the leakage.

(3)A person who contravenes subsection (1) or (2) or knowingly gives any information that is false in a material particular commits an offence and is liable on conviction to a fine at level 2 and to imprisonment for 6 months.

It is worth pointing out that MERS has been added to the list of scheduled agents which also includes SARS, H5N1, H7N9 etc. The secretary and Dr Hau discussed the matter and agreed the key phrase here was "that may pose a public health risk". We also agreed that the nature of the reported incident was such that it did not pose a public health risk and therefore did not need to be notified.

The concern in this context is identifying situations that might prove to be a health risk and consequently when accidents should be notified. If one of those in the room developed a high temperature might this be notified? An alternative way of interpreting this regulation is that any leakage (whatever that means) should be reported because there is a public health risk - however small that risk is.

The issue was discussed in the most recent Microbiology departmental Biosafety and Biosecurity meeting without firm conclusion. Questions were raised as to what would need notification and timing of that notification. Appendix 5b is the only document on the Centre for Health Protection website that relates to this type of accident and despite the documents title (Guidance on Notification of Leakage of Scheduled Infectious Agents in the Laboratory) it is basically a report form without any helpful guidance.

Members are asked their view of what constitutes "a leak" and what sort of incident would pose a "public health risk". Do members believe all accidents at BSL3 should be reported to government?

9. Briefing note on gene editing and gene drives (for information).
Gene editing and gene drives are receiving a lot of attention in Biosafety circles with a number of keynote addresses at this year's national and international Biosafety conferences. Appendix 6a attempts to summarize some of the issues and Appendix 6b is a set of frequently asked questions

10. Update on CDC Federal Select Agent Program (for information)
Following on from the for information point at the last meeting the program has now published what is in effect a situation report on initiatives that have been taken and what stage of implementation these measures have reached. For detail please see: -

https://www.cdc.gov/phpr/dsat/documents/DSAT-Program-Improvement-Initiatives-08092017.pdf.

The relevance to HKU is that at least one group in the University receives US NIH funding to work on select agents and is therefore subject to some oversight by this program (see point 14 on agenda).

11. Progress on proposed reviews of key international Biosafety Advice (for information)

11.1 The WHO Laboratory biosafety manual

The WHO Laboratory biosafety manual (Laboratory biosafety manual, Third edition. Geneva: World Health Organization; 2004 http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/) originally published over 30 years ago has provided practical guidance on biosafety techniques for use in laboratories at all levels. As the third edition was published in 2004 the need for a revision has been discussed by WHO and there is general agreement that a revision should be undertaken. In a talk by Dr Kazunobu Kajima (from WHO) at the American Biosafety Association conference in October 2015 (available on line:- https://absaconference.org/wp-content/uploads/2015/11/151006_VI_230_Kojima.pdf) referred to a three year program of work. This along with promised consultations with stakeholders (some of which is underway e.g. UK ACDP discussed some issue in its meeting in 2017) means the revision is unlikely to be available before 2019

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition

As mentioned at the last meeting a revision to the BMBL 5th edition is being considered by the NIH and the CDC. A virtual town hall meeting was held from April 4th to May 20th 2016 and a workshop on May 12, 2016 in Washington, DC at the National Academy of Sciences solicited opinions from stakeholders.

Minutes of this workshop are now available at https://www.nap.edu/read/23585/chapter/1 and a recent talk by one of the lead authors has been uploaded to US government office of science policy. Please see:- https://osp.od.nih.gov/wp-content/uploads/Session_III_Talk_Wilson.pdf. The intention is to add a number of new appendices some of which are substantive and I would think it likely that the new edition will not be available for several years possibly not before 2019/20

11.3 Revision of Part 3 of the UK Scientific Advisory Committee for Genetic Modification (SACGM) Compendium of Guidance

The SACGM Compendium of Guidance is being revised in a phased manner. The revised Part 3 of the Compendium, which relates to the containment requirements for genetically modified microorganisms, was available for review and comment via HSE's microbiological hazards on-line community. Those interested were asked to provide feedback on the drafted guidance via a feedback form before the end of 2 May 2016. From minutes of the SACGM committee it appears that the secretariat has had staffing issues in 2016 and that their work plan was modified so that the revision of the Compendium of Guidance resumed in 2017. It is unclear when the updates will be

approved and available. But of the revisions underway the approach of updating sections means that many of these will be available before the other advice detailed above.

12. Recent laboratory acquired infections and incidents in the news (for information)

12.1 Salmonella

On July 19th, 2017, CDC published an official notice (https://www.cdc.gov/salmonella/typhimurium-07-17/index.html) indicating that a multi-state outbreak of Salmonella typhimurium linked to microbiology teaching labs had been identified. This is the third outbreak associated with US microbiology teaching labs in the past six years. The biosafety community is being asked to assist in assuring that microbiology teaching labs are utilizing best practices for the safe handling of common pathogens. Both CDC (https://www.cdc.gov/salmonella/typhimurium-07-17/advice.html) and the American Society for Microbiology (ASM) (https://www.asm.org/index.php/education-2/22-education/8308-new-version-available-for-comment-guidelines-for-best-biosafety-practices-in-teaching-laboratories) have produced guidelines for microbiology laboratories.

12.2 Polio Type 2 accident and shedding

On 3 April 2017, a wild poliovirus type 2 (WPV2) spill occurred in a Dutch vaccine manufacturing plant. Two fully vaccinated operators with risk of exposure were advised on stringent personal hygiene and were monitored for virus shedding. Poliovirus (WPV2-MEF1) was detected in the stool of one, 4 days after exposure, later also in sewage samples. The operator was isolated at home and followed up until shedding stopped 29 days after exposure. No further transmission was detected. This was reported in Duizer et al (2017) Response to a wild poliovirus type 2 (WPV2)-shedding event following accidental exposure to WPV2, the Netherlands, April 2017. Euro Surveill. 22(21). pii: 30542. doi: 10.2807/1560-7917.ES.2017.22.21.30542

13 New guidance on safe working with arthropods published September 2017 (for information)

ISTR (Institute of Safety in Technology and Research – the body that administer professional qualifications for Biosafety in the UK) in consultation with HSE and the Advisory Committee on Dangerous Pathogens (ACDP) with input from the UK biosafety community and scientists who work with arthropods and GM insects have recently published the following guidance:-

"**Safe working with arthropods: Containment and control for work with uninfected, infected and transgenic animals in research**". As the title implies this covers research work with exotic and UK native species of arthropods (mosquitoes, biting midges and ticks) and GM insects that are vectors of virus diseases affecting animals (such as bluetongue virus or African horse sickness virus), and humans (such as Zika virus or dengue fever virus). The guidance is available at: -
http://www.istr.org.uk/docs/guidance%20on%20the%20containment%20of%20infected%20arthropods%20%20V1%20August%202017.pdf

14. CDC select agents team inspection of FMB BSL3 laboratory - on behalf of NIH (for information)

From 10th July 2017 to 13th July 2017 a team of 3 inspectors from CDC inspected the Centre for Emerging Infectious Disease BSL3 laboratory on the 5th floor of the Faculty of Medicine building on behalf of NIH. This involved a detailed almost forensic examination of all the policies, procedures and facilities. For example the paperwork alone examined was many thousands of pages requiring a trolley to move it. The inspection also includes presentations from the PIs on the work carried using NIH funds. The inspectors even examine many random vials from the freezer stocks to ensure the inventory record is consistent with the physical stock. They conduct interviews with selected staff including the safety officers, PIs, technicians and security staff and make a report which goes to NIH based on standard criteria. At the final meeting the lead investigator (who had visited several times previously) gave a summary of their findings. He indicated they were satisfied that the work was carried out securely and safely. They made a number of recommendations including i) improving training and refresher training documentation along with ii) more formal animal care documentation iii) introducing a document control system iv) carrying out more frequent internal audits sharing the finding with all staff v) undertaking annual safety and security exercises with the emergency services. In summary they said that they had a very positive overall impression of the facility.

15 NIH biosafety month (for information)

Every October the NIH office of policy sponsor National Biosafety Month. Their aim is to encourage institutions to highlight the importance of biosafety and to undertake activities to strengthen their biosafety programs. In past years during National Biosafety Months, NIH has promoted themes such as transparency, laboratory accountability, and public engagement. This year their theme is “promoting biosafety through good governance.”

A Federal Experts Security Advisory Panel (FESAP) has developed a document articulating guiding principles and best practices for biosafety and biosecurity governance. This document "Guiding Principles for Biosafety Governance: Ensuring Institutional Compliance with Biosafety, Biocontainment and Laboratory Biosecurity Regulations and Guidelines" is now available at: - https://www.phe.gov/s3/Documents/FESAP-guiding-principles.pdf

16. AOB

i. Specialist working group to oversee higher risk GOF experiments

Members may remember that at our October 2013 meeting we decided high risk gain of function work needed closer scrutiny to ensure that: - 1. Full consideration is given to the safety of the work and appropriate controls are in place. 2. Local debate is had about the risks and potential benefits of the work.3. International standards and regulations are followed - particularly those in place in the USA which would keep open funding opportunities from the USA. We proposed a small sub-committee including Prof Jin and Prof Bacon-Schone review the work and comment as they felt appropriate. As yet we have not activated this option because gain of function work has generally been avoided.

Appendix 7 contains an e-mail string from Professor Lau (Department of Microbiology) enquiring about the possibility of reviewing/approving work with MERS which might come under the banner of gain of function.

In the light of the advice given in Appendix 7 the secretary would appreciate advice on how to proceed with this request. There might be a complicating factor in that Prof Jin has some interest in genes from MERS and SARS.

17. Dates of next meetings.
To be determined and circulated once new committee arrangements are decided upon.