Agenda for the 19th meeting of the Biosafety Committee of the University of Hong Kong. (A sub-committee of the Health, Safety and Wellbeing Committee).

To be held on Thursday, November 22nd 2018, 10.30 a.m. Room 412 at Professorial Block, Queen Mary Hospital.

1. Introductions and Apologies

2. Terms of reference and membership of The Committee

TO NOTE:

Committee members are asked to note the following excerpts from the minutes of the first meeting of the University Committee on Health, Safety and Wellbeing held on March 8th 2018.

(a) AGREED (i) to recognise the Biosafety Committee as an official specialist subcommittee of this Committee, (ii) to approve the terms of reference originally given to the Biosafety Committee (Appendix 1 of Appendix C), subject to amendments being made to the terms of reference to reflect the replacement of SHEC by this Committee, and (iii) to amend the membership composition of the Biosafety Committee to include an appointee of the University Health Service (UHS) who could give advice to those exposed to biological hazards; and

(b) NOTED that the Director of UHS was willing to serve on the Biosafety Committee to provide advice on biological hazards.

TO CONSIDER:

The Terms of Reference and membership of The Committee. Note that the Terms of Reference have changed to reflect that The Committee is now a subcommittee of the newly established Committee on Health, Safety and Wellbeing.

BSC/19/01
BSC/19/02

3. Minutes of the 18th meeting of the Biosafety Committee (December 14th 2017)

TO CONSIDER:

The draft minutes of the previous meeting of the Biosafety Committee, circulated in October 2018 by e-mail.

BSC/19/03

4. Matters arising from the minutes of the 18th meeting (action points etc.)

TO CONSIDER:

At the 18th meeting it was agreed that biosafety documents should be reviewed every three years or more frequently if required. After taking up his post the current secretary has reviewed these documents and has suggested a number of minor amendments. Thus a revised table is presented.

BSC/19/06

At the 18th meeting The Committee was asked to consider guidance documents on the safe transport of infectious materials (BSC/19/04) and a risk assessment worksheet for clinical samples (BSC/19/05).

BSC/19/04
BSC/19/05

After review of all documents minor amendments to 4 further documents are presented. All changes are as set out below, the full documents are provided for context only.

Biological Safety Policy. Minor amendments on pages 11 and 42 to change hyperlinks whose target documents have been updated.

BSC/19/07

Minor update to retrovirus guidance on page 8; included reference to evidence of insertional mutagenesis by lentiviral vectors in human gene therapy trials (Schlimgen et al. (2016). This is relevant to an evaluation of risks using this vector system in any context.

BSC/19/08

Minor amendments to page 4 of RA1, the risk assessment form for work with biological agents. This is so that it can also be used to evaluate the risks from biological agents that may be incidentally present in experimental materials.

BSC/19/09

Minor amendments to page 4 of RA3, the risk assessment form for work with adenoviral vector systems. This is to insert some previously deleted text so that the advice on preliminary assignment of containment level now reads "Consideration should be given to increasing the containment measures if there is deliberate manipulation of host range, use of a serotype that is known to provoke an exaggerated immune response or where the site of disablement is not where the foreign gene has been inserted."

BSC/19/10

What is the opinion of committee members regarding these changes ?
Are committee members aware of any other areas where guidance would be helpful?

5. Introductory courses in Biosafety

TO NOTE:

Introductory Biosafety talks were given as follows:

4th September, to approximately 100 MBBS students, Faculty of Medicine, Li Ka Shing Faculty of Medicine, 21 Sassoon Road.

8th September, to approximately 100 Faculty of Medicine post graduate students, Li Ka Shing Faculty of Medicine, 21 Sassoon Road.

10th September, to approximately 80 prospective animal researchers, Li Ka Shing Faculty of Medicine, 21 Sassoon Road.

A detailed, day long briefing on work at BSL-3 was given to about 15 researchers working at the AIDS Institute on 24th August

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.

If members are aware of groups of staff or students who might benefit from biosafety briefings or more extensive training, please bring this to their attention. The safety office is generally able to facilitate requests for training given reasonable notice.

6. CULATR Applications

TO NOTE:

Since May 2018 The secretary has reviewed the safety aspects of 28 CULATR applications at the request of the LAU. In addition he has provided advice prior to submission on two other applications at the request of the PI.

7. Review of layout of the Biosafety section of the safety office web site

TO CONSIDER:

The secretary has reviewed the organization of material in the biosafety section of the safety office web site. While impressed with the comprehensive nature of the material provided, as a pair of "fresh eyes" it was felt that the long list of links on the present main biosafety page may make it difficult for users to locate material of relevance to them. A new version of the web site has been created that retains the existing material, but organizes it into a number of themed sub pages that hopefully make it easier to locate relevant material. The new version can be viewed at the following URL

http://www.safety.hku.hk/Temp/bio.html

The visual appearance of the test web site is much impaired compared to the original web site, in particular all the parts of pages that provide links to other parts of the safety office web site are non functional. This functionality would be restored if the revised web site was relocated to replace the existing web pages.

What is the opinion of the committee on the reorganization of the material ? Is it now grouped in a more logical way ? Has it enabled users to locate material that they were not previously aware was available on the web site ? Should the new layout be adopted, or can committee members suggest an alternative organization that would work better for them ?

8. GM Risk

TO CONSIDER:

A general review of currently available risk assessment advice, and the experience of reviewing CULATR applications submitted since May, has highlighted a potential shortfall in the assessment of GM risk. As a technology and broadly speaking GM techniques have a long history of safe use. Quite rightly the emphasis of existing advice is on the GM risks associated with use of viral vector systems, in addition to advice for those wishing to import or export GM materials. However the secretary is aware of some situations where there is a potential GM risk, and existing arrangements would not prompt a user to consider these risks in their experiment.

The main risk is experiments which aim to modulate the expression of a biologically active substances, either by use of viral vector systems that are themselves low risk, such as adeno associated virus (AAV), or in the context of GM organisms, almost always a mouse. At present there is no prompting to consider any potential harmful effects of the protein to be expressed or repressed. This is surprising as often the intention of the experiment is to produce a significant impact on the experimental system by modulating that gene product. There is evidence of harm arising from the use of GM techniques; there are a very small number of examples where modulation of levels of a gene product, usually an immunomodulator, has produced a severe outcome.

Some general guidance for GM risk assessment, outlining the situations where these severe events occurred has been put together for consideration.

BSC/19/11

To complement this a template generic GM risk assessment has been put together that can be used to assess GM risks in any context.

BSC/19/12

Clearly it would be not be productive for every experiment involving GM technology to be subject to a detailed GM risk assessment, as the vast majority of work is very low risk. Nevertheless where there is a reasonable expectation that

i) a biologically active substance will be made or repressed where there is evidence of a potential to cause harm to health or the environment

AND

ii) there is a reasonably forseeable mechanism by which that modulation could have effects in addition to those intended experimentally eg. after a needlestick injury, exposure to animal bedding or failure to inactivate waste adequately,

then it would be prudent to assess the risks posed by the gene product to be modulated.

What is The Committee's opinion on the current arrangements for addressing GM risk ? Should the above advice be made available and, if the above conditions are satisfied, a risk assessment conducted according to the above template ? It is proposed to build this question in to the safety assessment section of the revised format CULATR submissions.

9. Accident reporting at BSL3 for scheduled agents

TO CONSIDER:

An accident occurred in one of the University BSL3 facilities in 2017 which involved a minor spill of MERS. The details are contained in the attached document.

BSC/19/13

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 previous 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 a departmental Biosafety and Biosecurity meeting in 2017 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?

10. Oversight of GOF experiments involving "Enhanced Pathogens of Pandemic Potential (EP3)"

TO CONSIDER:

The secretary has been in discussion with colleagues in the School of Public Health and the Department of Microbiology regarding their request for an enhanced oversight mechanism for experiments which potentially increase the virulence or the infectivity of potential pandemic pathogens. There is no statutory requirement for this in Hong Kong Law, but it was felt that the setting up and the operation of such an internal mechanism would of value when seeking international funding or publishing research in international journals.
The attached document gives a definition of "an enhanced pathogen of pandemic potential."

BSC/19/14

A meeting was held on Tuesday 30th October in which an oversight mechanism based on internal peer review was agreed. A report of this meeting is attached.

BSC/19/15

At present it is envisaged that this mechanism will only be necessary for work taking place at BSL-3 or ABSL-3. All work with pathogens at this level, enhanced or otherwise, is already subject to an existing scrutiny mechanism because of the need to allocate resource in the limited number of BSL-3 laboratories. In the opinion of The Committee

will the need to undertake such work at BSL-3 capture all potential EP3 work, or is there a possibility of BSL-2 work that would fall under the EP3 definition ? Even if the starting point is a RG2 organism, is there the potential for work to be undertaken that would not need to take place at BSL-3 on safety grounds, but would still meet the definition of EP3 ? The secretary finds it difficult in practice to envisage a situation where this would be the case, but would welcome suggestions to the contrary. It should be noted that the BSL-3 oversight committee would not be aware of other work taking place in the University if it does not request access to the BSL-3 facilities they are responsible for.

11. AOB

A request for any items that committee members would like included on the agenda was circulated in September. If committee members have any items they wish to raise it would be helpful, but not essential, if they could contact the secretary in advance of the meeting.

12. Dates of next meetings.

To be confirmed with the chair. It is proposed that a meeting is held by circulation in April and that a meeting where committee members attend in person be scheduled toward the end of October 2019.