Minutes of the 1st Biosafety Committee Meeting, 23rd November 2006, 3rd Floor Library, Safety Office, James Lee Building. 14.15-16.15.

I. Introduction by the chairman. The chairman started by indicating that he was aware that Hong Kong lagged behind other countries in biosafety provision. The point was made that many overseas universities had appointed biological safety officers and set up biosafety committees over 15 years ago. Following several reviews of the management of health and safety in the University it was acknowledged that biosafety was an under resourced area. The committee was reminded that despite the lack of legislation in Hong Kong the University is committed to develop standards that are internationally accepted best practice and to this end Senate approved the appointment of a biological safety officer in 2004. In 2005 the University Safety Health and Environment Committee (SHEC) recognized that the next step in implementing best practice was to appoint a committee to oversee biological safety. The purpose of this first meeting of that committee was primarily to discus the mode of operation of the committee.

A wide ranging discussion then followed and a number of general points made which are summarized in the following points that were raised.

I1. A systematic approach is needed because a number of perceived "loopholes" in the current procedure

I2. The system adopted needs to be simple to encourage compliance

I3. The system needs to have as little bureaucracy as possible to gain acceptance.

I4. Secrecy and competition between PIs may decrease compliance.

I5. The committee was reminded by several members that the head of department (HOD) can be remote from some of the work going on in the department. (A HOD may not hear of work going on in the department until it is published was one view) Therefore it follows that the committee's effort to ensure safe working needs to be targeted at the level of the PI.

I6. If possible the committee needs to use systems that are in place, this will reduce bureaucracy. For example it may be possible to include a biosafety talk in the compulsory courses run for postgraduate students.

I7. The importance of training and raising the awareness of staff and students at all levels was emphasized by a number of committee members. The point was made that the aim of the committee should be to raise awareness to the same sort of level there is with CULATR applications. Everyone that does animal work knows they need to fill in an animal ethics form. Everyone who carries out work with potentially hazardous biological material should carry out an assessment of the risks along with assigning the appropriate measures to protect human health and the environment.

I8. Opportunities for instruction, information and training need to be maximized. The example of radiation safety was cited where workers are registered and attend a course during reading week before being allowed to work with radioactivity. It was suggested that this may be one way of improving information giving and training for the use of viral vectors. It was suggested that a mix of online and face to face training could be used to reduce the need for required contact time. This would be particularly useful if an individual could not attend a course.

I9. The decision of the Medical faculty to require attendance of RPG students at a safety awareness session and pass a multiple choice test was noted as one initiative in improving training. It was also pointed out that they monitor student attendance very closely and this would be a requirement for any course run on biosafety.

I10. The point was made that where approval for work with human subject's required ethical approval the process allowed decisions to be made at different levels. For undergraduates the PI with HOD knowledge could give approval, for taught postgraduate students the faculty ethical committee could give approval and staff applied directly to the main committee. The consequence of this is that the main committee has fewer proposals to assess. Feedback on the proposal is given to applicants, hopefully enabling them to make a better submission in the future.

The secretary indicated that departmental safety representatives and/or departmental safety committees may not have the necessary expertise to review a proposal in the detail required so although elements of this model may be applicable to some departments e.g. Microbiology, it may not be possible to implement fully in all departments.

I11. It was noted that a wide variety of students carry out experimental work in the University, including those from high school (including student summer interns) and the more familiar undergraduates, graduates and postgraduates. Any system of risk assessment and training will need to take this into account. It was agreed that the biosafety policy document should cover this in some detail to give appropriate guidance.

I12. One proposal that the committee discussed was to incorporate safety risk assessments into student thesis. This was thought to have a number of benefits including ensuring risk assessments are done and an ongoing one of raising awareness at the beginning of a research career.

I13. The secretary indicated that different countries place some organisms in different hazard categories. (US puts HIV, HBV and E.coli O 157 in a biosafety level 2 category while the UK and Europe place these agents at level 3.) The committee agreed that the University should follow the recommendations of the US Centre for Disease Control/National Institutes of Health BMBL 4th edition (the 5th Edition is likely to be available shortly) in this regard

Paper1

1.1 The secretary explained that the terms of reference are basically those approved by SHEC but they have been modified slightly to clarify them and reduce repetition.

1.2 The chairman indicated that the verbs describing the committee's responsibilities make it clear that its role will be an active process. The secretary said that he viewed all of these functions are part of his job as the Biological Safety Officer and felt the role of the committee was complimentary to his activities. He indicated that he could have set up a series of measures independently but felt it was important that the committee as part of the University management structure was involved. This would be likely to produce a more authoritative and imaginative consensus on the issues involved than he as an individual could come up with. Ultimately this should ensure better compliance with a sensible scheme of biosafety.

1.3 A brief discussion on the composition of the committee ensued. The point was made that some expertise in studies on plants would be appropriate. Dr Leung and Dr Lim indicated that they were comfortable with issues in this area as some of their research involved plant work.

1.4 It was noted that the committee had not appointed a senior member of technical staff. The secretary had mentioned to the chair the possibility of approaching Cindy Lee from Microbiology and due to a misunderstanding had not done so. He indicated that he would do this as soon as possible.

Paper 2

2.1 The committee briefly reviewed the current arrangement for biosafety approval of projects that went to outside funding agencies. The HOD is required to sign that all projects sent for outside funding e.g. RGC or RFCID are safe. As regards biosafety this is often carried out by using a checkbox form a blank version of which was included in the paper. It was felt that some of the questions could have been put differently.

2.2 Three examples (here, slightly modified to maintain anonymity) that illustrate the shortcomings of the current system were discussed.
a) Often in research projects an assay system or experimental protocol is developed that can be exploited more widely. In one case researchers developed a system for one viral agent (on an RGC grant that had been safety cleared) and then purchased *Mycobacterium tuberculosis* to assay in the same system without full discussion of the safety implications. *M. tuberculosis* is a significantly different safety risk and of much greater concern.
b) One group wanting to use adenovirus recombinants on asking advice they clearly had no real idea of the safety issues involved yet the project had been cleared through the current system.
c) Retrovirus vector systems are suitable for expression of genes in many different settings. When gene expression doesn't work with the system proposed in a grant it is quite natural to investigate the possibilities of whether a retrovirus e.g. lentiviruses would work. In the incident discussed a PI got his student to ask other students that are already using the system how get it to work with their gene. This may not have involved any risk

assessment or appreciation of safety issues on the part of the student wanting to learn about the system

Paper 3

3.1 The Chair had a prior commitment to fulfill and left shortly before the end of the meeting. It was agreed to carry on with the meeting in order to gauge the committee's opinions on the options presented in paper 3. The secretary agreed to meet with the chair and update him on the discussion. It was also agreed that the secretary would update Paper 3 in line with the discussion and circulate it to the committee for comment.

3.2 Some discussion regarding confidentiality was initiated and it was agreed that all submissions to the committee must be viewed as confidential and not discussed with persons outside the committee.

3.3 A proposal to combine option C and D of Point 3.6 appeared to meet with complete agreement from the committee. This option would mean that the committee believes all virus vector work along with all level 2 and 3 work should be thoroughly risk assessed.

3.4 the secretary mentioned the fact that in the UK annual reporting of projects to the central government used to be requirement of the legislation and this has now been dropped. Some Universities have found it a useful management tool to keep this going while others have also dropped the requirement of its PIs. The committee appeared to have mixed views about the need for annual reporting of ongoing projects. It was suggested that this topic might be returned to at a later date once the system had started.

Paper 4. It was acknowledged that the arrangements as they currently stand are unlikely to satisfy the NIH requirements for a properly constituted committee. It appeared to be the consensus of the committee that an outside member would be desirable and it was suggested that someone from the Department of Health might be invited to be a member

Paper 5. This was noted with the comment that some of the deadlines seemed ambitious. The secretary acknowledged this and suggested that they were aspirational targets and have some leeway associated with them depending when the committee felt the new system should be implemented.

The secretary also explained that he had hoped to provide sufficient guidance to inform and help assess each commonly used vector system. A guidance note with blank assessment form and example risk assessments would also be provided for each virus vector system. Guidance would also be provided on risk assessment for work with pathogens.

Paper 6. This was discussed briefly. The secretary indicated that other pieces of guidance would be produced in a similar format but would welcome suggestions for improvement. He pointed to the summary table of containment level for carrying out work as an example of the style that would be adopted.