Note of ISTR Biosafety Steering Group meeting – 25/10/2011 at University of Manchester

Present:

Jillian Deans
Anton dePaiva
June Freeland
Anne Hallam
Chris Perrons
Patrick Seechurn

Apologies received from: Jayne Thomas, Arthur Mitchell and Paul Jackett

Agenda item 1 – Agree revised terms of reference

1. A number of minor changes were agreed as follows:

- To remove "with the regulatory authorities" from first aim and add "nationally and internationally".
- To carry out a review of the membership of the steering group every three years and that the review would be initiated at the regional level; regional groups would be asked to consider their representatives on the group and propose new reps as necessary.
- Meetings would be chaired by whoever hosts.
- The immediate priorities would be amended to reflect actions already taken.

2. The issue of administrative support for the accreditation scheme was briefly discussed. While support was currently judged as being sufficient, the role was largely reactive (dealing with queries, issuing of certificates etc), and there may be a case for expanding the role to become more proactive eg to follow up course attendees to register as Level 1 Practitioners and to check and update the website. It was agreed that the current job description should be reviewed and a more detailed analysis carried out of resource needed to make the role more proactive before taking this further (possibly with USHA).

AdP to review current job description

3. Final draft to be sent to ISTR EC for approval (draft attached).

Action: JD to amend and present to ISTR EC

Agenda item 2 – working arrangements

4. Agreed that group would meet face to face at least twice a year and arrange other ad-hoc meetings via conference calls as required. If required, meetings could be scheduled at the same time as other planned biosafety meetings; the suggestion being to use the regional group meetings since this would also promote cross attendance between the groups.

5. Agreed that information about the BSG and its role would be prepared for the ISTR website.

JD to review/revise current material and circulate draft for comment

Agenda item 3 – Comments from HSE (and NaCTSO) on 2011 Biosymposium

6. PS had been contacted by HSE who had expressed concerns that they had not been invited to speak at the symposium. Earlier discussions had considered their attendance but given the final programme, it was felt that open discussion may be impeded with regulators present. However, their presence at future conferences would be discussed at the earliest opportunity and this would

be addressed in the planned letter to HSE from the ISTR Chair (informing them about the BSG and its role). The BSG would work with HSE to ensure that their contributions were consistent with the themes and aims of future symposia.

Agenda item 4 – Article in ISTR Bulletin

7. Concerns were expressed about the content of the article on the BSG in the current bulletin. It did not appear that anyone in the BSG had either contributed or been asked to comment on the text. It was agreed that, in future, the BSG would actively provide content for the bulletin.

Agenda item 5 - Arrangements for 2011 Biosymposium

8. Agreed that JD would chair morning session and JF the afternoon. So as to promote discussion in the afternoon session, three issues were identified which could be raised by members of the BSG (PS initially):

- Whether individuals had their own formal guidance on sealability testing?
- How do individual demonstrate competence to smoke test to satisfy HSE?
- How is fumigation validated (when/indicators used etc)

Agenda item 6 – Topics for 2012 symposium on culture

9. Four issues/subjects were identified:

- Quality vs safety – potential for this to be delivered by a keynote speaker
- How far do we go to test – industry vs academic approach but with a clear message about the impacts on research of not testing (despite resource implications)
- Physical containment of tissue culture laboratories - +ve vs negative pressure
- Value and role of testing for RCV – is it done, how and what is found.

All to consider speakers for the above topics and any additional issues in keeping with the theme

Agenda item 7 – Identify biosafety guidance documents needed by community

10. Number of suggestions had been put forward on Hasnet and at regional BSO meetings:

- Containment of FACS machines
- Sealability testing
- Connected programmes/significant change
- Containment of arthropods
- Containment of plant pathogens

11. Agreed that project plans would be prepared for any guidance being prepared and guidance should be based around the principles of good practice with examples of approaches to be taken, rather than recommending one particular solution. Suggested approach of guiding documents rather than guidance – nanotechnology guidance on HSE website developed with the nano-community was seen as a useful model to follow.

Agenda item 8 – Gap analysis working group report.

12. PJ had circulated a short report; CP indentified the main issues:

- Not a huge gap between CEN agreement and BSP scheme

- Main difference is that there is no level 1 and 2 in CEN document – suggestion for ensuring BSP scheme is aligned with CEN scheme would require review of Level 2 scheme to explicitly include certain aspects of Level 1.

13. It was agreed that ISTR would need to take a decision as to the need to align the current UK scheme (which was considered to more than meet the requirements of the CEN scheme) so that those accredited under the UK scheme could also be considered as meeting the CEN standard. The details of administration of the CEN scheme were not yet known, although there was some suggestion that EBSA might set up as an accrediting body.

ISTR EC to consider whether formal alignment with CEN scheme should be progressed

Agenda item 9 – Review of accreditation scheme (Levels 1 and 2)

14. A number of issues were discussed:

Level 1

- Not all members of the BSG had access to the current formal documentation in relation to the scheme, for example the documentation relating the assessment of course being accredited. A summary of this process was given. However, it was still not clear whether this accreditation related to the material being delivered, the trainers or else a combination of both. This had lead to issues following the franchising of training material from one provider to another where it was not clear whether the franchise included accreditation too. It was agreed that the lack of formally documented procedures covering franchising and re-accreditation has meant that the processes were not transparent or defensible in the event of a challenge. The latter was a particular concern in relation to an on-going re-accreditation of a provider.
- There was currently only one assessor available to accredit /re-accredit providers. This was a cause for concern as regards both their availability and that in the past, more than one assessor had reviewed the delivery of training so that a consensus, rather than individual view was given. It was not clear as to the procedure following assessment; who took the final decision as to whether to accredit or re-accredit?
- More assessors could be recruited from the "pool" of individuals currently preparing their portfolios for registration as Biosafety Professionals. However, they would need to be independent of any current training provider and also willing/able to give time to the process.
- It was agreed the current process of accreditation was vulnerable; an alternative approach was discussed. It was considered that it would be better to measure the learning outcomes of a course - using a standardised exam to be completed by all candidates rather than accrediting providers. This exam would be subject to a robust standardisation /validation process similar to that which exists in Universities.
- The BSG were conscious that this would require additional work but given that many members of ISTR were based in Universities, it was thought that there was a source of expertise readily available to help ISTR develop this further (NB: this was discussed at the Midlands and SW BSO meeting on 27/10 where one of their members was identified as having particular skills and knowledge of setting up courses and exam systems.)
- It was considered that the loss of revenue from the accreditation of providers could be off-set by provision of study days or workshops in preparation for the exam.

Action: ISTR EC to consider the options for continued and future administration of the Level 1 scheme

Level 2

- The value of mentors for the Level 2 scheme was discussed; a number of concerns were raised:
    a. None of the mentors had formally attained the Level 2 registration themselves
    b. Feedback from mentors was variable
    c. The mentor and assessor should not be the same person
- A workshop had been proposed for those currently registered under the grand-parent rights scheme but this had not taken place. It was agreed that this would still be of value to those currently assembling their portfolios as there were still uncertainties as to the manner in which the portfolio should be put together and the amount of evidence that was required. However, given that the deadline for submission for a large number of individuals is 31/12/2011, a quick decision was needed. It was suggested that if a workshop was held in early 2012, the deadline for submission of those attending could be extended eg submission no later than 6 months after the workshop.
- It was also suggested that these workshops or peer review groups could replace the current assigned mentor scheme provided they were held on a regular basis. In addition, a virtual peer review group, perhaps using a Hasnet list could also be set up to support those on the scheme.

15. It was agreed that the next meeting would be scheduled for January 2012 by conference call and that the next face to face meeting would take place in April 2012. The January meeting would consider further the agenda for the 2012 symposium with the aim of agreeing speakers and the programme at the April meeting.