MINISTRY OF HEALTH
SINGAPORE

MH 78:70

14 July 2014

CEO/Facility Operator, BSL-3 Facility
CEO/Facility Operator, ABSL-3 Facility
CEO/Facility Operator, BSL-2 Facility

COMPLIANCE TO THE BIOLOGICAL AGENTS AND TOXINS ACT AND ADOPTION OF GOOD BIOSAFETY PROCEDURES AND PRACTICES

We would like to bring to your attention of a recent incident involving the transfer of "presumably inactivated" *Bacillus anthracis* samples from a BSL-3 laboratory at the U.S. Centers for Disease Control and Prevention to three BSL-2 laboratories. This could have potentially exposed 84 workers from the three BSL-2 laboratories to the deadly anthrax bacteria. More details on the incidents and the after-action report are available in the references section.

2 The incident serves as a timely reminder to all facility operators and researchers on the importance of carrying out a thorough inactivation process of high risk group biological agents, such as the First and Second Schedule biological agents under the Biological Agents and Toxins Act (BATA); before deemed safe to be handled in a lower containment facility.

3 The Ministry of Health (MOH) would like to remind all facility operators who have in their possession of First and Second Schedule biological agents to be mindful of their duties and obligations in relation to such biological agents, as stipulated under Sections 27, 28 and 29, as well as Part V of the BATA.

4 Please note that it is the responsibility of the facility operator to ensure that the following measures are in place, including but not limited to:

a) Securing valid approval from MOH to possess and/or handle First and Second Schedule biological agents;
b) Ensuring that such biological agents are not to be transferred to another facility unless the receiving facility has been given the approval to possess the said First or Second Schedule biological agents; or
c) First and Second Schedule biological agents have to be **effectively inactivated** (to render non-infectious and unable to replicate itself under any condition) before they are allowed to be transferred to a facility without an approval to possess them. In such instances, the facility operator have to ensure that:

Ministry of Health, Singapore
College of Medicine Building
16 College Road
Singapore 169854
TEL (65) 6325 9220
FAX (65) 6224 1677
WEB www.moh.gov.sg

(i) The inactivation procedure is carried out in the facility specified in the approval to possess;
(ii) The inactivation procedure has been assessed and proven to be effective in inactivating the biological agent;
(iii) The inactivation procedure must be devised/reviewed/approved by the Biosafety Committee and the facility operator;
(iv) Efficacy studies must be carried out to validate all the inactivation procedures, specific to the types of biological agent; and such results must be documented and made accessible when requested;
(v) Records of every inactivation cycle and transfer of the inactivated materials must be documented and made accessible when requested; and
(vi) Endorsement and/or approval must be secured from the facility operator before any inactivated biological agents are being transferred out of the facility to any other facilities.

5 We seek your cooperation and compliance to the BATA, and adherence to all good biosafety practices.

6 For further clarification, please contact the officers from the MOH Biosafety Team at 6634 6469 or 6325 9205 or 6325 8459.

Dr Se Thoe Su Yun
Principal Biosafety Specialist
Regulatory Policy Branch
For
Director of Medical Services

References:

Press Release from the US CDC entitled "CDC Director Releases After-Action Report on Recent Anthrax Incident; Highlights Steps to Improve Laboratory Quality and Safety"
http://www.cdc.gov/media/releases/2014/p0711-lab-safety.html

Biological Agents and Toxins Act:
http://statutes.agc.gov.sg/aol/search/display/view.w3p;page=0;query=DocId%3A6b6eae33-48b3-4aeb-bbbd-651b14629c01%20Depth%3A0%20ValidTime%3A01%2F10%2F2011%20TransactionTime%3A22%2F09%2F2011%20Status%3Ainforce;rec=0;whole=yes

Ministry of Health, Singapore
College of Medicine Building
16 College Road
Singapore 169854
TEL (65) 6325 9220
FAX (65) 6224 1677
WEB www.moh.gov.sg