

POLICY FOR VALIDATING ATTENUATED STRAINS OF BL3¹ ORGANISMS,

Adopted by COMS on 26 May 2006

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Objective: To verify the identity of attenuated strains of BL3 organisms prior to receipt.

This requirement to validate strains applies to all BL3 agents. Select agents must be validated by NERCE. Non-select agent BL-3 strains can be tested in other labs and documentation must be provided to the institutional biosafety officer for review by COMS.

All attenuated strains of BL3 **Select Agents** obtained from outside sources must be shipped directly to the NERCE/BEID laboratory for validation.
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1. Possession and research involving attenuated BL3 organisms must be approved by COMS.
2. Validation.
 - a. Until attenuation is validated all experiments with attenuated BL3 organisms must take place at BL3 unless lesser containment is approved by COMS.
 - i. Harvard has no BL4 laboratories. Hence attenuated BL4 agents cannot be validated at Harvard.
 - ii. Validation procedures must be approved by COMS.
 - a) Approval by two reviewers with the necessary expertise will suffice.
 - iii. Validation must be carried out in an approved COMS registered laboratory equipped for and experienced with strain validation.
 - iv. Documentation of validation testing must be submitted to COMS or NERCE/BEID for approval and permanent archiving.
 - b. After the initial validation, it is recommended the attenuated BL3 organism be grown and aliquoted in quantities sufficient for use until the project is completed. This will be the seed stock for future cultures.
 - i. Attenuated BL3 organisms must be stored in a secured, limited access facility.
 - ii. A detailed, legible, log of their use must be kept by the investigator.
3. Maintenance. Ensuring attenuated strains remain attenuated over long periods.
 - a. Vials of Seed Stock and Working Stock derived from Seed Stock should be sterilized and discarded after a single use.
 - i. Hence numerous aliquots should be generated by the receiving laboratory.
 - ii. Working Stock must be derived only from Seed Stock.
 - iii. When Seed Stock is nearly exhausted a sample of Master Stock can be obtained from NERCE/ BEID.
 - a). Revalidation is also acceptable if Master Stock is not available.

¹ An attenuated BL3 organism is one that can be safely used at BL2 or (rarely) BL1 containment and procedures.

4. Transfer to another Laboratory.
 - a. Attenuated BL3 organisms or their derivatives may not be transferred to another laboratory without COMS approval.
 - b. Attenuated BL3 Select Agents or their derivatives may not be transferred to other laboratories.
 - i. Only NERCE / BEID is permitted to distribute attenuated Select Agents.
5. Failure to comply with these provisions may be the basis for disciplinary action.