

Biocontainment requirements for vaccine production from and quality control of the reassortant candidate vaccine virus IVR-153

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Safety testing of the candidate reassortant vaccine virus IVR-153 has been completed according to WHO protocol¹. The safety tests for IVR-153 were conducted by the WHO Collaborating Centre for Reference and Research on Influenza, Melbourne, Australia, by CSL Limited, Parkville, Australia and by the Australian Animal Health Laboratories (AAHL), Geelong, Australia.

Results of analysis of virus shedding in the lungs and lung pathology² indicate that the **IVR-153** reassortant candidate vaccine virus is attenuated in ferrets relative to the wild type A/California/7/2009 (H1N1)v virus.

Therefore, as attenuation has been demonstrated for the above reassortant candidate vaccine virus **IVR-153**, vaccine production using fully trained and competent staff in accordance with national safety guidelines may proceed at BSL-2 enhanced level, as described in the WHO Technical Report Series No. 941¹, Annex-5.

¹ http://www.who.int/csr/resources/publications/swineflu/trs941_annex5/en/index.html

² Detailed test reports will be sent to the laboratories that have been supplied with the vaccine viruses