## Biocontainment requirements for vaccine production from and quality control of the reassortant vaccine candidate viruses IDCDC-RG15, NIBRG-121 and X-179A

Safety testing of the candidate reassortant vaccine viruses (IDCDC-RG15, NIBRG-121 and X-179A) has been completed according to WHO protocol[1]. The safety tests for IDCDC-RG15 and X-179A were conducted by the WHO Collaborating Centre for Surveillance, Epidemiology and Control of Influenza in the U.S. Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA. The safety tests for NIBRG-121 were conducted by the WHO Essential Regulatory Laboratory at National Institute for Biological Standards and Control (NIBSC), Potters Bar, Hertfordshire, United Kingdom.
Results of analysis of virus shedding in the lungs and lung pathology[2] indicate that,

- The **IDCDC-RG15** reassortant vaccine candidate virus is attenuated in ferrets relative to the wild type A/Texas/15/2009 (H1N1)v virus
- The **NIBRG-121** reassortant vaccine candidate virus is attenuated in ferrets relative to the wild type A/California/7/09 (H1N1)v virus
- The **X-179A** reassortant vaccine candidate virus is attenuated in ferrets relative to the wild type A/California/4/2009 (H1N1)v virus

Therefore, as attenuation has been demonstrated for the above three reassortant candidate vaccine viruses, 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. 941[1], 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