

Biosafety Update

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Revisions to the NIH Guidelines for Synthetic Nucleic Acids

- **Draft Federal Register notice will be provided for review to individual members of the Biosafety Working Group and the RAC members to ensure it accurately reflects the final recommendations outlined at the June 2010 RAC meeting.**

Proposed Revision for Registration of BL1 Transgenic Rodents 75 FR 42114

Appendix C–VII. Generation of BL1 Transgenic Rodents via Breeding

The breeding of two different transgenic rodents or the breeding of a transgenic rodent with a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at BL1 containment, will be exempt from the *NIH Guidelines* if:

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Both parental rodents can be housed under BL1 containment, and neither parental transgenic rodent contains the following genetic modifications:

- a) More than 50% of the genome of an exogenous virus from a single Family of viruses; or**
- b) A transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and**

–It is anticipated that the transgenic rodent that results from this mating will not:

- a) Contain more than 50% of an exogenous viral genome from a single Family of viruses.**

Comments Received in Response to FR notice

- 9 comments received; all supportive
- One comment asked for clarification of how much gammaretroviral LTR sequence must be present to not be exempt
 - In the final FR notice, additional explanation will be added to clarify sufficient gammaretroviral LTR sequence to control expression of the transgene (not smaller fragments of homologous sequence not acting as a promoter)