



## CHANGES TO NOTIFICATIONS OF LOW RISK DEALINGS (NLRDs) AND DEALINGS NOT INVOLVING INTENTIONAL RELEASE OF GMOs (DNIRs)

### NLRDs which became licensable as DNIRs from 31 March 2007

From **31 March 2007** changes to the list of dealings that are not NLRDs (Part 3, Schedule 3 of the *Gene Technology Regulations*) means that some previously notified Notifiable Low Risk Dealings (NLRDs) now require a licence for a Dealing not involving an Intentional Release (DNIR). If you are working on such an NLRD (mainly *in vitro* dealings with non-3<sup>rd</sup> generation lentiviral vectors), you must apply for (and be granted) a DNIR licence by **31 March 2008**.

### DNIRs which became NLRDs from 31 March 2007

If you currently hold a DNIR licence for a dealing which now only requires an NLRD under the amended regulation 13, your IBC can surrender your licence using the new '*Combined NLRD Notification & DNIR Surrender*' form available on the OGTR website at: [www.ogtr.gov.au/pubform/forms.htm](http://www.ogtr.gov.au/pubform/forms.htm). After **1 July 2007**, you only need to request a surrender of the DNIR (because new NLRDs only need to be recorded by the IBC and notified to the Regulator on an annual basis). Please note that should you wish to convert a DNIR that is now classified as an NLRD, you must do so before your DNIR licence expires.

### Can I keep my DNIR licence for a dealing that is now considered an NLRD ?

Yes. If you wish to retain your licence, you may simply follow your existing licence conditions.

### Reporting requirements for NLRDs

From **1 July 2007** IBCs are no longer required to notify the Regulator of new NLRDs before commencement of the dealing. Any new NLRDs commencing within the financial year must be reported by the IBC to the Regulator once a year via the organisation's annual report. However, you must keep a record of all current NLRDs and provide them to the Regulator if requested to do so. More information on these notification requirements can be found on the OGTR website at [www.ogtr.gov.au/pubform/forms.htm](http://www.ogtr.gov.au/pubform/forms.htm).

### NLRDs that may be an exempt dealing

Due to the changes in the classification of dealings in the Regulations, some existing NLRDs may now meet the requirements for an exempt dealing (Part 1, Schedule 2 of the amended Regulations). Examples include some *in vitro* dealings with non-retroviral vectors or dealings with microorganisms newly added to the list of exempt/host vectors (Part 2, Schedule 2 of the amended Regulations). You may choose to continue to conduct dealings according to the requirements of your existing NLRD or according to the requirements for exempt dealings. If your NLRD has now become an exempt dealing no notification to OGTR is required.

### **NLRDs suitable for containment in certified PC1 facilities**

The removal of specific containment requirements for exempt dealings from **1 July 2007** was linked to the removal of some of the dealings from classification as exempt dealings, including some dealings that were reclassified from NLRDs to exempt dealings on 31 March 2007.

Dealings with GM rats and mice, *in vitro* dealings with non-retroviral vectors carrying oncogenes or some *in vitro* dealings with retroviral vectors now fall into a new category of NLRD (described in Part 1, Schedule 3 of the amended Regulations) that will require containment in facilities certified by the Regulator to at least PC1. If you commenced work on such a dealing as an exempt dealing **you DO need to obtain approval from your IBC for the NLRD.**

However, if the dealing was notified prior to 31 March 2007 as an NLRD, the NLRD authority remains and you do not need to apply again if it is now reclassified as a 'PC1' NLRD. Dealings which are described in the requirements of Part 2 of Schedule 3 of the amended Regulations (*i.e.* all former NLRDs) will still require containment in a certified PC2 facility.

*More information about the changes can be obtained from the Office of the Gene Technology Regulator website at [www.ogtr.gov.au](http://www.ogtr.gov.au), by email to [ogtr@health.gov.au](mailto:ogtr@health.gov.au) or by telephoning 1800 181 030*