

Australian Government

Department of Health and Aged Care Office of the Gene Technology Regulator

Model Form – Record of Assessment for a Notifiable Low Risk Dealing (NLRD) – Updated as per changes commencing 1 July 2020

Regulation 13B(a) of the Gene Technology Regulations 2001 requires an IBC that has assessed an NLRD proposal to make a record of its assessment, in a form approved by the Regulator, and specifies the information that this record must contain.

Regulation 13B(b) further requires that an IBC that has assessed a proposed NLRD must give a copy of the record of assessment of the NLRD to the person or accredited organisation that submitted the proposal to the IBC. The IBC should be able to demonstrate that this has occurred.

In making an NLRD record of assessment (RoA) and recording that it has been given to the proponent, IBCs have the option of using this model form or another recording system/format of their own. Provided the record contains all the information specified in Regulation 13B(a)(i)-(x), the record will be considered to be in a form approved by the Regulator.

An IBC may also require that proponents submitting an NLRD proposal for assessment use this model form (or another form of their own design), in order to ensure that all relevant details are provided and simplify making a RoA.

Notifiable Low Risk Dealing (NLRD) Reporting Form – SmartForm

In July 2018, the Notifiable Low Risk Dealing (NLRD) Reporting Form was released in a SmartForm format. This enables a person or organisation required to give the Regulator a record of a proposed dealing using an online reporting form, streamlining the processes for notification and receipt. All persons and organisations submitting notifications of NLRDs to the Regulator are encouraged to use this online reporting form.

A document titled *Guidance on making a Record of Assessment for an NLRD and on responsibilities for those undertaking NLRDs* has also been prepared to assist NLRD proponents and IBCs in complying with NLRD requirements. It is strongly encouraged that this guidance document be consulted when preparing an NLRD proposal or making a RoA.

IBC NLRD Identifier:

(A unique identifier assigned by the IBC for the particular NLRD proposal.)

Regulation 13B (a) requirement:

 (i) the identifying name of the dealing to be undertaken that was given by the person or accredited organisation that submitted the proposal; 	
 (ii) a description of the dealing to be undertaken; (Consider the breadth and scope of all the activities in relation to the dealings including any importation, transport, storage or disposal of the GMO – refer to Section 10 of the Gene Technology Act 2000 for a definition of "deal with" in relation to dealing with a GMO) 	

IBC NLRD Identifier:		
(A unique identifier assigned by the IBC for the particular NLRD proposal.)		
Regulation 13B (a) requirement:		
(iii) Committee assessment whether the dealing is a kind of dealing mentioned in Part 1 or Part 2 of Schedule 3, and not mentioned in Part 3 of Schedule 3;		
(For a dealing to be an NLRD, it must be listed in Part 1 or Part 2, and not listed in Part 3, of Schedule 3. Dealings which are not NLRDs may be either exempt dealings or licensable dealings; A RoA is not required for such dealings.)		
<i>If the proposed dealing has been assessed as not being an NLRD, the dealing must not be undertaken without obtaining an appropriate authorisation under the Gene Technology Act 2000.</i>		
 (iv) if the Committee has assessed the dealing as being an NLRD mentioned in Part 1 or 2 of Schedule 3 (and not mentioned in Part 3 of Schedule 3) – which kind of dealing in those Parts, that the dealing is; 		
(As an NLRD may involve a number of scheduled kinds of dealings, all the relevant items must be listed).		
 (v) the date of Committee's assessment of the dealing; 		
(Preferably in dd/mm/yyyy format. The IBC may also wish to calculate and record the end date of the NLRD, being the day 5 years after the date of assessment, regulation 13(1)(d).		
 (vi) the persons or classes of persons considered by the Committee to have appropriate training and experience to undertake the dealing; 		
 (vii) the facilities or classes of facilities the Committee considers to be of the appropriate physical containment level and type for the dealing, having regard to the requirements of subregulation 13(2); 		
(viii) the name of the Committee that assessed the proposal;		
 (ix) the name of the person or accredited organisation that submitted the proposal; 		

 IBC NLRD Identifier:

 (A unique identifier assigned by the IBC for the particular NLRD proposal.)

 Regulation 13B (a) requirement:

 (x)
 the name of the person or persons proposing to undertake the dealing¹.

1 Note: The name of an individual person is only required here if the "person or persons proposing to undertake the dealing" is **actually** an individual who is not associated with an organisation, university, research institute, company etc.

IBC Chair or delegate with authority to sign		
Printed name:	Signature:	
Job title:	Date:	

IBC NLRD Identifier:				
Regulation 13B (b) requirement:				
give a copy of the record of assessment to the person or accredited organisation that submitted the proposal to the Committee. (Another method may be used to demonstrate that this record has been given to the person or organisation that proposed the NLRD).	(name of assessing IBC representative)			
	(signature of IBC representative) and received by:	(date)		
	(name of organisation that submitted the (name of person / representative of the su organisation)	ubmitting		
	(signature)	(date)		