



Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

File: 2008/023809

Ms Jennifer Wan
Quality Assurance Manager
AMS Laboratories Pty Ltd
8 Rachael Close
SILVERWATER NSW 2216

Dear Ms Wan

I refer to the application by AMS Laboratories Pty Ltd received by this Office on 24 April 2013 to vary Cert 2649 to extend the period of certification and to apply the conditions of certification as they appear in version 3.2 of the *Guidelines for Certification of a Physical Containment Level 2 Laboratory* (PC2 guidelines).

In accordance with section 87 of the *Gene Technology Act 2000* (Commonwealth) and corresponding State law, I hereby vary the above-mentioned certification to extend the period of certification for 5 years and to apply the conditions of certification as they appear in version 3.2 of the *Guidelines for Certification of a Physical Containment Level 2 Laboratory*. Please ensure that training and training records for people who undertake dealings in the facility are updated where necessary to comply with the new guidelines.

The revised certification details are as follows:

Certification number	Cert 2649
Variation number	Var 6942
Name of facility (‘the certification’)	Rooms 1 to 13, 20 to 26, 29 to 31, WI1 to WI5, Cool Room and Associated Corridors, Ground Floor, AMS Laboratories Pty Ltd
Facility level & type	PC2 Laboratory
Guideline version	Version 3.2 of the <i>Guidelines for Certification of a Physical Containment Level 2 Laboratory</i> effective 1 March 2013
Certification holder	AMS Laboratories Pty Ltd
Variation effective from	24 May 2013
Expiry date	2 June 2018

All previous conditions attaching to the Certification are revoked.

In place of the revoked conditions, I impose the following conditions:

- The facility must comply with Part B of version 3.2 of the *Guidelines for Certification of a Physical Containment Level 2 Laboratory*, effective 1 March 2013, which can be found on the OGTR website (www.ogtr.gov.au).

In accordance with Part 12 Division 2 of the Act, you have the right to seek a review of my decision to vary the conditions of the certification. In accordance with section 181 of the Act, an application for review may be made in writing to the Regulator within 30 days of receiving this letter. The Regulator will personally review the decision. In accordance with subsection 181(4), the Regulator may make a decision affirming, varying or revoking my decision, and if the Regulator revokes the decision, make such other decision as the Regulator thinks appropriate.

If you are not satisfied with the decision made by the Regulator under section 181 of the Act you may lodge an appeal under the *Administrative Appeals Tribunal Act 1975*.

However, if you do have any concerns, please feel free to discuss them first with me.

Thank you for your cooperation with the regulatory system.

Yours sincerely

A handwritten signature in black ink that reads "Ian Coleman". The signature is written in a cursive style with a long, sweeping underline.

Ian Coleman
Delegate of the Gene Technology Regulator
23 May 2013

Encl. Signs for the facility