

Application for a variation to a medicinal cannabis licence under the *Narcotic Drugs Act 1967* – Licence Variation Type 3

Preliminary Questions

1.		pes the application relate to a medicinal cannabis licence issued by the Office of Drug Control (ODC) ander the <i>Narcotic Drugs Act 1967</i> (the Narcotic Drugs Act)?
		Yes - proceed to Question 2
		No - Variations cannot be sought until a licence has been granted under the Narcotic Drugs Act
2.	Do	oes the proposed variation relate to changes affecting any of the following?
	•	the layout of a site for a particular licensed premises
	•	the floorplan of a particular licensed premises (except where the change to the floor plan is as a result of adding or removing an activity authorised by the licence at that premises)
	•	authorised activities
	•	adding an authorised person
		Yes - proceed with this application form
		No - a different application form may be required, please see the ODC website
Ν	ote	, an 'authorised person' includes:
	a)	the licence holder;
	b)	the person who holds a managerial or supervisory position that has direct control over the activities authorised by the licence;
	c)	the person responsible for controlling on a daily basis the activities authorised by the licence.

Important information

This is an application to the Secretary of the Department of Health and Aged Care made under section 10N of the Narcotic Drugs Act to vary a medicinal cannabis licence granted under that Act.

Irrespective of the person(s) completing this licence variation application form, the licence holder is accountable for the accuracy of the information entered and submitted as part of the application, including any supporting documents.

The application may be withdrawn at any time before a decision has been made, but the application fee is not refundable. If you decide to withdraw your application, then an email to this effect should be sent to MCS.application@health.gov.au.

Implementation of variations

Variations sought through this application must not be implemented by the licence holder until a decision approving the application, when made by the delegate, is notified in writing by the ODC. It should be noted that the lodgment of an application to vary a licence does not constitute approval to commence or continue activities that would be unauthorised under an existing licence. Conducting authorised activities where facilities or security arrangements have not been approved may be a breach of the licence and unlawful.

Privacy

The ODC collects a variety of personal information in the course of performing its functions. Personal information is defined in the Privacy Act 1988 (Cth) (Privacy Act). Your personal information is protected by law under the Privacy Act, which contains the Australian Privacy Principles. The ODC is part of the Australian Government Department of Health and Aged Care. The Privacy Policy for the Department is available at www.health.gov.au.

The ODC may validate any information provided with this application with Commonwealth, State and Territory law enforcement authorities and State and Territory regulatory, planning and/or infrastructure authorities.

Providing Incorrect Information

Under Divisions 136 and 137 of the *Criminal Code Act 1995*, it is an offence to provide a false or misleading statement, information, or documents to the Commonwealth, including as part of an application to vary a licence.

Submitting the application

Licence details

SECTION 1

Once completed, please email this application form along with all relevant supporting documentation to the ODC at mcs.application@health.gov.au.

Licer	nce noider name:				
Licer	nce number:				
SECT	ION 2 Variation purpose				
Indic	ate the purpose/s for which you are seeking to vary the licence:				
	1. Vary layout of site (complete sections 3 and 7 of this form)				
	2. Vary floorplan, where there are otherwise no changes to the authorised activities approved to be undertaken at the licensed premises (complete sections 4 and 7 of this form)				
	3. Vary, add or remove an authorised activity to the licence (complete sections 4 (if applicable), 5 and 7 of this form)				
	4. Add an authorised person to the licence (complete sections 6 and 7 of this form)				
	If multiple person/s are proposed to be added, note how many				

Provide a description of the proposed changes to layout affecting approved site plan for a licensed premises, this must include a comparison between what is currently approved and the proposed changes, including details of the areas within the site to which the changes relate.				
Additional licence variation application requirement - If the proposed changes to the site plan include changes to the security measures at that particular licensed premises, a Licence Variation Type 2 application is also required.				
SECTION 4 Variation to floor plans for a licensed premises				
Provide a description of the proposed changes to floor plans for a particular licensed premises, this must include a comparison between what is currently approved and the proposed changes, including details of the specific areas (eg. rooms) to which the changes relate.				
Additional licence variation application requirement - If the proposed changes to the floor plans include changes to the security measures at that particular licensed premises, a Licence Variation Type 2 application is required, unless section 5 of this application is also completed.				
SECTION 5 Vary, add or remove an authorised activity				
Provide the address of the existing location at which the new or varied activity will take place				

Variation to layout affecting approved site plans

SECTION 3

Indicate which new or varied activities will be undertaken at the existing location			
Cultivation			
Production			
Manufacture			
Any other changes relating to authorised ac culture, or changing packaging, transport, storag	tivities (including commencing cultivation using tissue ge, disposal or destruction arrangements)		
	w or in supporting documents on the basis for which you e manufactured drug/s, as required by the Narcotic Drugs		
Where the varied activity involves changes to packaging, transport, storage, disposal or destruction arrangements, provide details about the proposed activities in the space below or in supporting documents.			
Where the new or varied activity includes cultivation using tissue culture, provide details about the proposed activities in the space below or in supporting documents. This should include any information about the impact the use of tissue culture for cultivation may have on other previously approved aspects of the licenced premises and operations; such as any bearings on security access or maintenance, storage, or on operational matters relating to people, policy, or procedures, and record keeping. In addition, the area/s in which tissue culture activities will be undertaken must be clearly labelled on the floor plan and submitted with this application.			
Do the proposed changes to vary or add an authorised activity result in a change to floor plans?	Yes – complete section 4.		

Do the proposed changes to vary or add an authorised activity result in a change to security measures?	☐ Yes − a Licence Variation Type 2 application is required.☐ No				
SECTION 6 Add authorised persons to the I	icence				
Provide the following information for each person proposed to be added to the licence as an authorised person:					
• Name					
 Position title 					
Description, including any of the following	g:				
a. the licence holder;					
 the person who holds a managerial or activities authorised by the licence; 					
c. the person responsible for controlling on a daily basis the activities authorised by the licence.					
 Site at which person will undertake authorised activities (where licence holder has more than one authorised site listed on the licence) 					
Provide details on the role the of additional authorised person/s. Indicate whether the person/s listed will undertake or directly supervise persons undertaking activities under the licence.					

Do any of the above persons currently reside of	overseas?	☐ Yes	☐ No	
If the answer to the previous question was yes, advise how the licence holder will purport to meet the condition of a medicinal cannabis licence to employ or engage suitable staff (see in particular section 10F of the Narcotic Drugs Act and section 18 of the Narcotic Drugs Regulation) for employees who reside overseas.				
For each additional person proposed to be listed as an authorised person on the licence, provide the following documents:				
Completed informed consent form				
Document requirement - These documents must be submitted at the same time as this application form.				
SECTION 7 Declaration and consent				
I am authorised by the licence holder to subn	nit this prop	osal to vary a licence o	n its behalf.	
I declare that, to the best of my knowledge, all the information in this proposal is true, correct and complete. I am aware that giving false or misleading information is a serious offence – see Division 136 and 137 of the <i>Criminal Code Act 1995</i> .				
Signature: insert image or print out and sign:	Name:			
	Date:			
	Email Addr	ess:		
	Phone Nun	nber:		

Version control

Updates to this document will occur automatically on the Office of Drug Control website and the revision table below will list the amendments as they are approved.

Date	Version	Amendments	Approved by
July 2023	1.0	Initial publication	ODC