



Australian Government  
Department of Health  
Office of Drug Control

# Guideline: Record Keeping and Reporting

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## Version control

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## Introduction

The *Guideline: Record Keeping and Reporting* (the Guideline) is intended to assist licence applicants and holders in designing and meeting standards that are required for record keeping and reporting matters related to cultivation, production and manufacture of medicinal cannabis.

Cannabis is a narcotic drug with a high illicit value. Amendments to the *Narcotic Drugs Act 1967* (Cth) (the Act) in 2016 provide a legal basis for cultivation of cannabis plants and production of cannabis and cannabis resins for medical and scientific purposes, through the introduction of medicinal cannabis licences, cannabis research licences and manufacture licences (cannabis licences).

The purpose of these legislative amendments is to make cannabis available for medicinal and related research purposes, while simultaneously ensuring that the risk of diversion is minimised. The aim of this Guideline is to assist in this objective.

The illicit value of cannabis makes the risk of diversion a significant one requiring sound and comprehensive controls. The [Guideline: Security of Medicinal Cannabis](#) addresses the requirements related to the physical and procedural security of medicinal cannabis, while the [Guideline: Fit and Proper Persons and Suitable Staff](#) addresses the requirements related to personnel security. This Guideline outlines measures to enable the monitoring and reporting of cannabis related activity and to support effective auditing and investigations.

The Office of Drug Control (ODC) is part of the Commonwealth Department of Health and is designated with the responsibility for regulating the cultivation and production of cannabis for medicinal purposes and the manufacture of medicinal cannabis products under the Act. ODC assesses all applications for cannabis licences and makes determinations to either refuse or grant a licence. ODC also performs inspections of cannabis cultivation, production and manufacturing sites to monitor compliance with the Act, the associated Regulations and with the specific conditions of each licence.

## Scope of this document

This document organises the information set out in the Act, Regulations and licence conditions to assist a licence applicant or holder in understanding, developing and maintaining arrangements related to record keeping and reporting of theft or loss of cannabis.

The Guideline describes mandatory requirements that the licence holder **must** comply with and provides examples of how this can be achieved.

This Guideline addresses your:

- record keeping and reporting arrangements
- ability to report on cannabis transactions, including for consumption to manufacturers or distributors, to destruction, or for other supply purposes (such as research)
- capability to support the regulator (ODC) in monitoring cannabis activity.

ODC will review your records and your overall reporting arrangements through the ongoing inspection and compliance framework.

## Compliance with these Guidelines

The Guideline uses the word **'must'** to indicate a mandatory requirement and the word 'should' to indicate a suggested method for achieving that expectation.

Where the word **'must'** is used, you have no discretion and will be required to demonstrate how your arrangements meet that expectation. Where the word 'should' is used, you will be required to demonstrate how your arrangements meet that expectation but there is some flexibility for you to show that your arrangements equate to, or are better than, those outlined in the Guideline.

Your record keeping and reporting arrangements will become part of your licence conditions and, once accepted, and the Department of Health will expect that you can demonstrate these arrangements when facilities are inspected.

### *Truthfulness*

The record keeping, reporting and monitoring requirements are extensive and require the disclosure of a significant depth of information. While ODC accepts that mistakes can be made, it is important to undertake your best endeavours to be comprehensive in record keeping and monitoring.

Applicants are also advised that in applying for a cannabis licence, or conducting activities under that licence, a person may commit an offence if the person provides false or misleading information in relation to that application or in the provision of information when requested to provide information by the ODC on behalf of the Commonwealth (see section 137.1 of the Criminal Code).

## International and domestic law

The amendments to the Act were implemented to enable the cultivation of cannabis for medicinal and scientific purposes in a way that is compliant with Australia's international obligations with the *Single Convention of Narcotic Drugs 1961* (the Single Convention).

The purpose of the Single Convention is to provide an international framework that recognises the medicinal value of narcotic drugs and ensures that narcotic drugs are available for such purposes while preventing their abuse and diversion. As a signatory to the Single Convention, Australia is committed to complying with the obligations within it, including designation of a single agency to licence and control cannabis cultivation and annual reporting to the International Narcotics Drug Control Board (INCB) on volumes of production and manufacture.

The Department of Health works in partnership with other Commonwealth agencies such as the Department of Agriculture and the Australian Border Force. We also have close relationships with state and territory jurisdictions looking at cultivation, production and cross-jurisdictional licencing requirements. We work closely with law enforcement agencies, both at the Commonwealth and state and territory levels, sharing information to maintain the integrity of the medicinal cannabis scheme.

## Reporting to INCB

Under the Single Convention, parties are required to inform the INCB of quantities of cannabis materials cultivated, produced, manufactured and used at each stage of the product supply chain to substantiate domestic requirements and forecast future requirements.

Appropriate record keeping and reporting on the part of licence holders forms a core part of assisting the Commonwealth in meeting these obligations. Furthermore, implementation of methodical and accurate record keeping procedures contributes to the management of the risk of diversion of cannabis for illicit uses.

To support our international reporting obligation, licences will be conditioned with a range of information components around both actual and estimated cultivation, production and manufacture. Note that many of these are explicitly covered by information requirements under permits outlined in the Act, and as further specified in the *Narcotic Drugs Regulations 2016*.

Reporting and forecasting requirements will include:

- details of cultivation area
- number of plants cultivated
- drying mechanism and average weight loss (where drying is conducted)
- wet and dry weight of crops produced (total)
- wet and dry weight of crops produced (components)
- end of year stock levels of crops produced (wet and dry weight)
- transactions of cannabis along the supply chain (including sale or physical movements)
- purpose of production (medicinal or research – defined by your licence type)
- forecast production for the next calendar year
- forecast end of year stock for the next calendar year

These reports require quantities of plants, cannabis produced, and/or cannabis resin produced.

Note that the separation of total and component weights is to allow for the removal of the herbal flower in some production processes.

In outlining the transactions along a supply chain, note that this includes any movement of materials for production or manufacture, to destruction, to consumption, or to a research purpose.

## Record Keeping and Reporting

A licence holder should ensure that information created, sent and received in the course of conducting their business is appropriately recorded for the purposes of:

- compliance with obligations under licence conditions, the Act and Regulations
- corporate memory and repeatable decision making
- ensuring the integrity of information assets
- facilitating business continuity as employees change over time
- responding to auditing or inspectorate requirements, which may include unannounced inspections
- meeting your security arrangements to record access to cannabis and to cannabis cultivation, production or manufacture sites.

The level of detail to be included in a particular record will need to factor in the complexity of the issue being addressed and any regulatory requirements that apply to the particular record.

Sound policies will be required to implement procedures for record keeping facilitating compliance with the Act, Regulations and licence conditions. Once created, records should be managed in a system that supports their transmission, reporting and tracking.

You are required as a condition of your licence to provide details of the arrangements in place to undertake record keeping activity.

### **Mandatory requirements for record keeping**

The Act (section 10D(f)) enables a condition to be imposed on a cannabis licence relating to documentation and record keeping in respect of activities to which the licence relates. This Guideline explains record keeping requirements in relation to cannabis plants, cannabis and cannabis resin, along with expectations of how these records should be kept and examples of how to meet these expectations.

The requirement will be included within licence conditions, and must be complied with for the duration of any cannabis licence that is granted, including post surrender of a licence where applicable. In the event of non-compliance with licence requirements, a cannabis licence may be suspended or revoked and, if appropriate, the matter referred to the relevant law enforcement agency for further action.

### **Mandatory requirements for reporting**

Section 20 of the Regulation prescribes the matters that the licence holder must notify ODC of as soon as practicable. A licence holder must as soon as reasonably practicable notify of:

- the theft or suspected theft of cannabis from a cannabis site
- the loss of suspected loss of cannabis from a cannabis site or any other place, including during transportation
- a discrepancy or suspected discrepancy in the number of cannabis plants or quantity of cannabis materials in the possession or under the control of a licence holder.

The differences between these events can be subtle. *Theft* refers to the act of stealing or wrongful taking and is a criminal offence. In the situation of known or suspected theft, the licence holder must notify the relevant law enforcement agency. *Loss* refers to the situation where the whereabouts of cannabis is unknown and it is not clear that theft has occurred. Loss could be the result of miscommunication or misplacement of cannabis.

A *discrepancy* in the number or quantity of cannabis in the possession or control of a licence holder applies to the situation where the expected number of cannabis plants or the size of the cannabis plants is different to what is expected. This could be the result of changes in growing conditions that results in plant death or stunted growth, the failure of seeds to germinate or signs that the type growing is not what is expected.

Should such circumstances arise, the licence holder must notify ODC and await direction. If a security breach has compromised security measures, then the licence holder must take steps to secure the cannabis site and the cannabis.

The mandatory requirements and key concepts related to record keeping and reporting are outlined further under Annex A – Requirements and Examples.

## Annex A – Requirements and Examples

### 1. Record keeping

**Mandatory requirement:** It will be a condition of your licence that the licence holder **must** have record keeping arrangements in place to record the amounts of cannabis that, during the period of the licence, the applicant: cultivates and obtains; maintains for the purposes of propagation; produces and stores; supplies to the holder of a manufacturing licence or a medicinal cannabis licence that authorises the production of cannabis; and/or destroys or disposes of.

Expectations	Rationale	Example
Records should be created as close as possible to the event to which they relate, by a person with the appropriate oversight of the activity to which the record relates.	This is to ensure that record keeping is accurate and timely in order to prevent errors or neglect.	Record created by employee undertaking the stocktake at the same time that the activity is being performed.  Regular internal procedures for verify amounts of cannabis on site.
Records should be managed in a system that supports the use, tracking and understanding of records.	This is to ensure that records are readily available for reporting to ODC as required and accessible during inspection activities by ODC.	Manual or digital filing protocols.  Software systems.  Version controls.
The licence holder should have procedures in place to facilitate access to records during an inspection by ODC (including unannounced inspections).	Verification of records will be an important activity during an inspection. This ensures that records can be viewed.	On site records or movement of relevant records to the site for inspections.  Access to digital systems.
The records should be stored in a way that maintains continuity.	This is to prevent the loss of records through natural disaster, criminal damage or negligence.	Records backed up off site.  Fire and flood proof facilities.



Expectations	Rationale	Example
Employees responsible for the maintenance of records should be clearly identifiable.	This is to ensure that the people managing records understand their obligations and to enable trace back in the event of a discrepancy.	Clearly documented procedures and role accountabilities.
Distribution of records should be limited to those with a legitimate business need to access the records.	This is related to procedural measures to prevent the distribution of information further than necessary.	Policies, access controls and procedures to limit the number of people who need to know information.
Records produced by a licence holder should be subject to appropriate physical, technological and administrative security safeguards to prevent unauthorised use, disclosure, theft, loss or other misuse.	So that sufficient barriers are in place to prevent deliberate and accidental unauthorised access to information.	Locked filing cabinets, restrictions to office access or alarm systems.  Passwords, encryptions and firewalls on any digital records.  Security clearances, access restrictions, staff training and confidentiality agreements.
The licence holder should record details of plant mortality to reconcile with permit requirements	This will account for any losses and enable the reconciliation of amounts of cannabis.	Plant mortality register that lists the number of plants that die.
The licence holder should have records that document chain of custody of the cannabis during transportation	To ensure that the handling of cannabis while being transported can be traced and tracked in the event of a discrepancy, theft or loss.	Registers that are signed by people involved in handling and transporting the cannabis.
Licence holders should ensure that appropriate resources are allocated to implementing and accurately maintaining their record keeping arrangements.	So that adequate time is available to complete records and facilitate compliance with reporting requirements.	Standard Operating procedures that embed record keeping activities.  Sufficient staff resources to ensure record keeping can be undertaken.

## 2. Reporting – stock and forecasts

**Conditional requirement:** in applying for a permit, the licence holder **must** provide information relating to the size of a cannabis crop, the number of plants, and the amount of cannabis or cannabis resin produced. As part of the conditions on a licence, the licence holder will be required to provide information necessary to support INCB reporting.

Expectations	Rationale	Example
Records should include the number of plants cultivated, the size of the growing space and the yields.	Differing means of production will result in different plant spacing, number and ultimately crop sizes.	Records of plants per permit and detail of cultivation space.  Internal procedures to verify amounts of cannabis
The licence holder should have mechanisms to record separation of plant components and undertake both wet and dry weighing of crops.	This is to manage the risk of diversion given both the high illicit value of dried cannabis flower, and the substantial difference in weight of cannabis between wet and dry conditions.	Procedures to track and weight cannabis along the production process.  Practices around internally tracking crops.
The licence holder should maintain records of all transactions involving cannabis distribution or movement events.	Understanding of the movements of cannabis for supply, destruction, production or any other purpose is a diversion risk control.	Registers of cannabis movements or transactions.  Examples under plant mortality and chain of custody (above) are also relevant to this control.
The licence holder should provide annual forecasts of anticipated production and projected 'end of year' stock for each calendar year.	Such forecasts allow ODC to oversee supply and prevent unnecessary stockpiling of cannabis.	Annual reporting arrangements with ODC.

### 3. Reporting – incidents

**Mandatory requirement:** The licence holder **must** have arrangements in place to ensure that ODC is notified of actual and suspected events involving:

- a security breach at, or unauthorised access to, a cannabis site
- a theft or loss of cannabis
- a discrepancy in quantity of cannabis
- a serious incident involving cannabis

Expectations	Rationale	Example
In the case of known or suspected criminal activity (theft or breach), the licence holder should immediately engage with their local law enforcement agency.	Law enforcement agencies are the first point of contact in response to a criminal act.	Incident response procedures contain contact details for local law enforcement agency.
The licence holder should provide ODC with formal, written notification of any such events.	This is to ensure that ODC can respond appropriately and to allow for consideration of any potential licence or permit breaches.	<p>Emails are the preferred method of written communication to ODC.</p> <p>ODC will work with licence holders to rectify inadvertent condition breaches.</p>
The licence holder should notify ODC immediately after identifying the event.	<p>This is to allow ODC to respond to any immediate issues.</p> <p>Note: such reporting should only be made after law enforcement reporting occurs, and after actions to secure the site and/or respond to safety concerns have been addressed.</p>	<p>ODC maintains an out of hours contact telephone number and requests follow-up email correspondence to clarify and formalise reports.</p> <p>ODC will work with licence holders to rectify inadvertent condition breaches.</p>

Expectations	Rationale	Example
<p>The licence holder should provide ODC with a description of the matter being reported, including but not limited to:</p> <ul style="list-style-type: none"><li>• details of the volume of cannabis unaccounted for</li><li>• when and how the issue was detected</li><li>• when and how the event was believed to occur</li><li>• the current status of security at the cannabis site</li><li>• any action taken by the licence holder</li><li>• any records that can support investigation into the matter.</li></ul>	<p>This information will assist ODC in responding to the situation and ensures that the licence holder has gathered relevant facts about the matter.</p>	<p>Development of incident management protocols including incident report forms to submit to ODC.</p> <p>Provision of security records, access registers and documented records of stock levels.</p>

## Definitions

The following words are defined specifically for use within this document. Where a word is not defined below, the definition should be taken to be the same as the Act or Regulations and where not defined in legislation, as defined in the Macquarie Dictionary.

Word	Definition
Cannabis	For ease of interpretation, where the term cannabis is used in this document it is taken to mean cannabis plant (including seeds), cannabis, or cannabis resin as defined in the Act.
Cannabis site	Means the physical location including the buildings, rooms and designated areas where activities authorised under a cannabis licence occur.
Handling	Includes stacking, stowing, storing, transporting, loading, unloading and any operation incidental to, or arising out of, any of those operations.  ( <i>Narcotic Drugs Act 1967</i> , section 3)
Production	Means the separation of leaves, cannabis and cannabis resin from the plants from which they are obtained.  ( <i>Single Convention on Narcotic Drugs, 1961</i> , Article 10)