



Australian Government

AHCMDC302 Apply regulatory and quality requirements to the production of medicinal cannabis

Release: 1

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Modification History

Release	Comments
Release 1	This version released with AHC Agriculture, Horticulture and Conservation and Land Management Training Package Version 6.0.

Application

This unit of competency describes the skills and knowledge required to ensure that medicinal cannabis production processes comply with regulatory requirements and the organisation's quality system and procedures.

The unit applies to individuals who carry out skilled work in medicinal cannabis production processes. They may not be directly responsible for developing procedures for compliance with regulation and quality systems; however, they are required to be aware of the existence of legislation and the Good Practices Standards framework, including the impact it has on the organisation's arrangements in place to ensure compliance and quality of the product.

No licensing, legislative or certification requirements apply to this unit at the time of publication.

Pre-requisite Unit

Nil

Unit Sector

Medicinal Cannabis (MDC)

Elements and Performance Criteria

Elements	Performance Criteria
Elements describe the essential outcomes.	Performance criteria describe the performance needed to demonstrate achievement of the element.
1. Identify regulatory requirements for medicinal cannabis production	1.1 Identify legislation, regulations and standards relevant to the production of medicinal cannabis 1.2 Investigate purpose and intent of regulatory requirements 1.3 Identify roles and responsibilities of authorities responsible for

Elements	Performance Criteria
Elements describe the essential outcomes.	Performance criteria describe the performance needed to demonstrate achievement of the element.
	administering requirements 1.4 Identify requirements of licensing for medicinal cannabis cultivators and manufacturers
2. Apply regulatory requirements to work practices	2.1 Identify workplace policies and procedures in relation to own work responsibilities in medicinal cannabis production processes 2.2 Review work practices to ensure compliance with regulatory requirements 2.3 Identify and report instances of non-compliance and potential problems according to workplace procedures
3. Identify and apply quality practices for production of medicinal cannabis	3.1 Identify quality requirements for the production of medicinal cannabis 3.2 Determine critical control points for work area 3.3 Conduct a safety hazard analysis and risk assessment 3.4 Monitor work area, materials, processes and crop to ensure compliance with quality requirements, hygiene and health and safety procedures 3.5 Identify and report instances of deviation and potential problems according to workplace procedures
4. Complete records to comply with regulatory and quality requirements	4.1 Record details of cannabis material receipted at site, stored on site and supplied from the site 4.2 Record details of cultivation processes that trace plant batch as it moves through production processes 4.3 Record hygiene and sanitation activities 4.4 Record health and safety requirements, including incident reports 4.5 Record details of plant, pest and disease monitoring, including test methods, results and control 4.6 Record details of fertigation and climate, including environmental control data and inputs 4.7 Identify and report instances of deviation and non-compliance in record-keeping according to workplace procedures

Foundation Skills

This section describes those language, literacy, numeracy and employment skills that are essential for performance in this unit of competency but are not explicit in the performance criteria.

Skill	Description
Reading	Access legal and quality documentation from a variety of sources to determine compliance requirements
Writing	Complete workplace documentation using accurate and legible data and appropriate terminology, and cross-check for errors
Numeracy	Interpret numerical data from sampling results and control gauges

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
AHCMDC302 Apply regulatory and quality requirements to the production of medicinal cannabis	Not applicable	The unit has been created to address an emerging skill or task required by industry	Newly created

Links

Companion Volumes, including Implementation Guides, are available at VETNet: - <https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=c6399549-9c62-4a5e-bf1a-524b2322cf72>

Assessment Requirements for AHCMDC302 Apply regulatory and quality requirements to the production of medicinal cannabis

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Performance Evidence

An individual demonstrating competency must satisfy all of the elements and performance criteria in this unit.

There must be evidence that the individual has effectively monitored the production of medicinal cannabis to ensure compliance with legislation and quality requirements, including:

- identified and applied legal and regulatory requirements and elements of quality standards that apply to production processes in own area of responsibility
- assessed own work area for critical control points, safety and risks
- completed accurate records for production processes in own area of responsibility, including records that cover all of the following on at least **three** occasions:
 - cultivation processes
 - traceability
 - hygiene and sanitation
 - health and safety
 - monitoring, sampling and control
 - identified and reported instances of deviation, potential problems or non-compliance.

Knowledge Evidence

An individual must be able to demonstrate the knowledge required to perform the tasks outlined in the elements and performance criteria of this unit. This includes knowledge of:

- national, state and territory legislation, regulations and standards relevant to the production of medicinal cannabis
- legislative and regulatory responsibilities required of licensed cultivators and manufacturers of medicinal cannabis
- roles and functions of commonwealth government authorities responsible for administering the legislation, including record requirements
- Good Practices Standards and organisation quality systems relevant to the production of medicinal cannabis, including:

- Good Agricultural and Collection Practices (GACP) in relation to cultivation and harvesting of plants, and quality and consistency of products
- Good Manufacturing Practices (GMP) in relation to pre-processing and quality of products
- principles of GACP and GMP in relation to:
 - cultivation and production processes
 - traceability, including validation of inputs
 - hygiene and sanitation
 - health and safety
 - monitoring, sampling and control
 - documentation processes
- organisational record-keeping requirements.

Assessment Conditions

Assessment of the skills in this unit of competency must take place under the following conditions:

- physical conditions:
 - skills must be demonstrated in a medicinal cannabis production site or an environment that accurately represents workplace conditions
- resources, equipment and materials:
 - workplace quality system
 - workplace recording system
- specifications:
 - access to legislation and regulations related to the production of medicinal cannabis
 - workplace quality procedures
 - workplace procedures relating to the production of medicinal cannabis, including health and safety, hygiene and sanitation, recording and reporting requirements.

Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards.

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